GEMSTAR™

For use with the following list numbers:

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Technical Service Manual

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430-600203-004 (A, 2013-11)	Fourth issue Front matter -- Delete copyright statement. Throughout -- Replace ® with ™ for Hospira and third-party products most prominent and first use only. Section 4 -- Add lithium battery useful life period. Section 5 -- Add lithium battery useful life period and instruction to return pump to Hospira for replacement. Update infuser maintenance test name to performance verification test. Explain onboard test and advanced tests. Update volume accuracy test and add advanced distal and proximal occlusion tests. Section 6 -- Delete Morgan Hill address for returns. Back page -- Update Hospira contact information for returns. Delete trademark statement. Update IEC symbols list. Add new copyright statement and update part number.

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Section 1

INTRODUCTION

The GemStar™ is a single-channel infuser designed for use in home care and hospital settings.

The infuser kit contains the following components:

- GemStar infuser
- Two AA disposable batteries
- System Operating Manual

Note: Some international configurations contain a table-top 220 V_{AC} mains adaptor with a separate power cord.

1.1 SCOPE

This manual is organized into the following sections:

- Section 1 Introduction
- Section 2 Warranty
- Section 3 System Operating Manual
- Section 4 Theory of Operation
- Section 5 Maintenance and Service Tests
- Section 6 Troubleshooting
- Section 7 Replaceable Parts and Repairs
- Section 8 Specifications
- Section 9 Drawings
- Appendix
- Index
- Technical Service Bulletins

If a problem in device operation cannot be resolved using the information in this manual, *contact Hospira (see Section 6.1, Technical Assistance)*.

Specific instructions for operating the device are contained in the *GemStar System Operating Manual*. Provision is made for the inclusion of the system operating manual in *Section 3* of this manual.

Note: The terms “infuser” and “device” are used interchangeably throughout the manual.

Note: Figures are rendered as graphic representations to approximate actual product. Therefore, figures may not exactly reflect the product.

1.2 CONVENTIONS

The conventions listed in *Table 1-1* are used throughout this manual.

Table 1-1. Conventions

Convention	Use	Example
Italic	Reference to a section, figure, table, or publication	*(see Section 6.1, Technical Assistance)*
[ALL CAPS]	Keys	Press [YES/ENTER] to continue.
ALL CAPS	Display messages	The infuser displays END OF INFUSION
Bold	Emphasis	**CAUTION: Use proper ESD grounding techniques when handling components.**

Throughout this manual, warnings, cautions, and notes are used to emphasize important information as follows:

WARNING: A WARNING CONTAINS SPECIAL SAFETY EMPHASIS AND MUST BE OBSERVED AT ALL TIMES. FAILURE TO OBSERVE A WARNING MAY RESULT IN PATIENT INJURY AND BE LIFE-THREATENING.

CAUTION: A CAUTION usually appears in front of a procedure or statement. It contains information that could prevent hardware failure, irreversible damage to equipment, or loss of data.

Note: A note highlights information that helps explain a concept or procedure.

1.3 ACRONYMS AND ABBREVIATIONS

This section contains the acronyms and abbreviations that appear in the text of this manual.

A Ampere
AC Alternating current
A/D Analog-to-digital
ADC Analog-to-digital converter
CPU Central processing unit
CRC Cyclic redundancy check
DC Direct current

DMM	Digital multimeter
ECG	Electrocardiogram
EEG	Electroencephalogram
EEPROM	Electrically erasable programmable read-only memory
EL	Electroluminescent
EMC	Electromagnetic compatibility
EMG	Electromyogram
EMI	Electromagnetic interference
ESD	Electrostatic discharge
ETO	Ethylene oxide
FET	Field effect transistor
FPGA	Field programmable gate array
hr	hour
Hz	Hertz
IC	Integrated circuit
IO	Input/output
IV	Intravenous
kHz	Kilohertz
LCD	Liquid crystal display
LED	Light emitting diode
mA	Milliampere
mcg	Microgram
mg	Milligram
MHz	Megahertz
mL	Milliliter
ms	Millisecond
mV	Millivolt
PFI	Power fail input
PIC	Programmable integrated circuit
PWA	Printed wiring assembly
PWM	Pulse width modulator
RAM	Random access memory
ROM	Read-only memory
RPM	Revolutions per minute
TPN	Total parenteral nutrition
UART	Universal asynchronous receiver/transmitter

V	Volts
V_{AC}	Volts alternating current
V_{CC}	Collector voltage supply
V_{DC}	Volts direct current
V_{PWR}	Primary power source
V_{rms}	Volts root mean squared
VTBI	Volume to be infused
µA	Microampere
µs	Microsecond

1.4 USER QUALIFICATION

The infuser is intended for use at the direction or under the supervision of licensed physicians or certified healthcare professionals who are trained in the use of the infuser and the administration of parenteral fluids or drugs. Training should emphasize preventing related IV complications, including appropriate precautions to prevent accidental infusion of air.

1.5 ARTIFACTS

Non-hazardous, low level electrical potentials are commonly observed when fluids are administered using infusion devices. These potentials are well within accepted safety standards, but may create artifacts on voltage-sensing equipment such as ECG, EMG, and EEG machines. These artifacts vary at a rate that is associated with the infusion rate. If the monitoring machine is not operating correctly or has loose or defective connections to its sensing electrodes, these artifacts may be accentuated so as to simulate actual physiological signals. To determine if the abnormality in the monitoring equipment is caused by the infuser instead of some other source in the environment, set the device so that it is temporarily not delivering fluid. Disappearance of the abnormality indicates that it was probably caused by the electronic noise generated by the infuser. Proper setup and maintenance of the monitoring equipment should eliminate the artifact. Refer to the appropriate monitoring system documentation for setup and maintenance instructions.

1.6 ELECTROMAGNETIC COMPATIBILITY

The GemStar is compliant with IEC/EN 60601-1-2 (2001), and has been tested and found to comply with electromagnetic compatibility (EMC) limits for the Medical Device Directive 93/42/EEC (EN 55011 Class B and EN 60601-1-2:2001). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation *(see the system operating manual)*.

CAUTION: Portable and mobile RF communications equipment, such as cellular telephones, two-way radios, Bluetooth™ devices, and microwave ovens in close proximity to the infuser may affect or degrade performance of the device. Operation of the infuser under such conditions should be avoided.

There is a shared responsibility between manufacturers, customers, and users to assure that medical equipment and systems are designed and operated as intended. Medical electrical equipment requires special precautions regarding electromagnetic compatibility.

The electromagnetic environment should be managed to permit the infuser to perform as intended without disturbing other equipment. The infuser should not be used adjacent to or stacked with other equipment. If the device must be used adjacent to or stacked with other equipment, monitor the equipment to assure there is no electromagnetic interference, and verify normal infuser operation.

1.7 INSTRUMENT INSTALLATION PROCEDURE

CAUTION: Infuser damage may occur unless proper care is exercised during unpacking and installation.

CAUTION: Do not place the infuser in service if it fails the self test.

The instrument installation procedure consists of unpacking, inspection, and self test.

1.7.1 UNPACKING

Inspect the shipping container as detailed in *Section 1.7.2*. Use care when unpacking the infuser. Retain the packing slip and save all packing material in the event it is necessary to return the infuser to the factory. Verify the shipping container contains a copy of the system operating manual.

1.7.2
INSPECTION

Inspect the shipping container for damage. Should any damage be found, contact the delivering carrier immediately.

CAUTION: Inspect the infuser for evidence of damage. Do not use the device if it appears to be damaged. Should damage be found, contact Hospira *(see Section 6.1, Technical Assistance)*.

Inspect the infuser periodically for signs of defects. Also inspect the infuser after repair or during cleaning. Replace any damaged or defective external parts.

1.7.3
SELF TEST

CAUTION: Do not place the infuser in service if the self test fails.

At power-on, the infuser immediately enters an initialization mode and performs the following self tests:

- RAM test
- ROM checksum calculation
- Motor control test
- Stuck key test
- PIC watchdog test
- CONFIG register test
- Battery voltage test
- Power loss completion test
- CRC verifications on all RAM areas protected by CRCs
- CRC on calibration data stored in the EEPROM
- Calibration data verification

The initialization mode completes in approximately 30 seconds. During this time the infuser displays a message that the self tests are being performed. If any test fails, the infuser alarms.

Note: The device does not infuse during the initialization mode.

After successful completion of the initialization mode, if there is not a current program in the infuser, the device enters programming mode so the user can enter a new program.

If a program is already in the infuser, the user may:

- Use the current program. The infuser enters stop mode after the program is reviewed.
- Enter a new program. The infuser enters programming mode, then enters stop mode after the program is reviewed.

  Note: If the infuser has been powered-off for less than five minutes, a program review is not required.

See *Figure 1-1* for an illustration of the infuser.

1.8 OVERVIEW

The following sections describe therapy options, differences between therapies, safety features, power sources, and basic operation of the infuser.

1.8.1 THERAPIES

The GemStar offers the following seven types of therapy:

- Pain Management
- Total Parenteral Nutrition (TPN)
- Intermittent
- Weight Dosed
- Continuous
- mL/hr Only
- Variable Time

Note: The availability of these programs may vary, depending upon the configuration of the infuser in use.

1.8.2 CONFIGURATION DIFFERENCES

The infuser is shipped from the factory with one of the configurations described in *Table 1-2*. The infuser configuration is easily identified by the end cap color.

Table 1-2. Configuration List Numbers

Therapies	13000 (Blue)	13100 (Gray)	13150 (Yellow)
Pain Management	✓		✓
TPN	✓	✓	
Intermittent	✓	✓	
Weight Dosed	✓	✓	
Continuous	✓	✓	
mL/hr Only	✓	✓	
Variable Time	✓	✓	

1.8.3
SAFETY FEATURES

Table 1-3 describes the special safety features of the GemStar.

Table 1-3. Safety Features

Safety Feature	Description
Proximal occlusion detection	Strain gauge
Distal occlusion detection	Strain gauge Settings: low, medium, and high sensitivity
Air-in-line detection	Ultrasonic settings: 0.5 mL, 2 mL, and Off
Motor monitoring circuit	Redundant and independent monitoring systems
Motor parameter monitoring	Motor encoder and camshaft flag monitored by optical sensor
Self tests	Initialization and self test at power-on Continuous self tests during operation

1.8.4
POWER SOURCES

The infuser can be powered by two internal AA disposable batteries, an external rechargeable battery pack, AC mains adaptor, or docking station. External supply voltage must not exceed 3.3 V_{DC}.

Install two fresh, disposable AA batteries for backup power when using an external power source. The infuser will continue to operate on backup power if the external power source fails.

CAUTION: To assure proper operation when using internal batteries, always replace both batteries with fresh, disposable AA batteries when a change is required. Use of rechargeable batteries in the battery compartment is not recommended.

CAUTION: Always connect to a grounded AC outlet when using the AC adaptor. Use only an AC adaptor specifically labeled for use with the GemStar to charge the battery pack. During charging, if the battery pack becomes hot to the touch, immediately disconnect from AC power and contact Hospira Technical Support Operations.

CAUTION: Do not touch exposed connectors on the bottom of the infuser. Exposed connectors are susceptible to electrostatic discharge (ESD) damage.

1.8.5
OPERATION

The infuser is microprocessor-based and is programmed using a 23-key keypad on the front of the device (*see Figure 1-1*). The 16-character-by-4-line backlight display indicates the status of the infuser.

The infuser has up to seven therapies available, depending on its configuration. Delivery rates and bolus dosage amounts are programmed in one of three units of measure: milliliters (mL), milligrams (mg), or micrograms (mcg). A loading dose is programmable for immediate delivery or delayed delivery. Bolus doses can be programmed to begin delivery on-demand.

To program the infuser, the operator selects the following:

- Therapy type
- Delivery type: volume delivery (mL) or mass delivery (mg or mcg)
- Concentration (only if mass delivery is selected)
- Delivery rate
- Loading dose, if desired
- Bolus dose, if desired
- Total amount to be delivered: volume to be infused (VTBI)

If mass delivery is selected, the infuser automatically converts mg or mcg to the closest number of tenths-of-mL. The amount of fluid delivered is shown on the display. When a bolus is programmed, a minimum lockout time between boluses must also be programmed. In addition to the lockout time, the operator can also program the maximum total volume that can be delivered in a selected period.

The infuser contains a time-of-day clock and event history storage capability. The program settings, significant events that take place while a protocol is running, and the associated time and date, can be reviewed on the display. The event history can be printed to a compatible printer or downloaded as an ASCII text file to a computer with the use of the GemStar serial printer cable.

For specific instructions regarding infuser operation and optional system components, refer to the *System Operating Manual*.

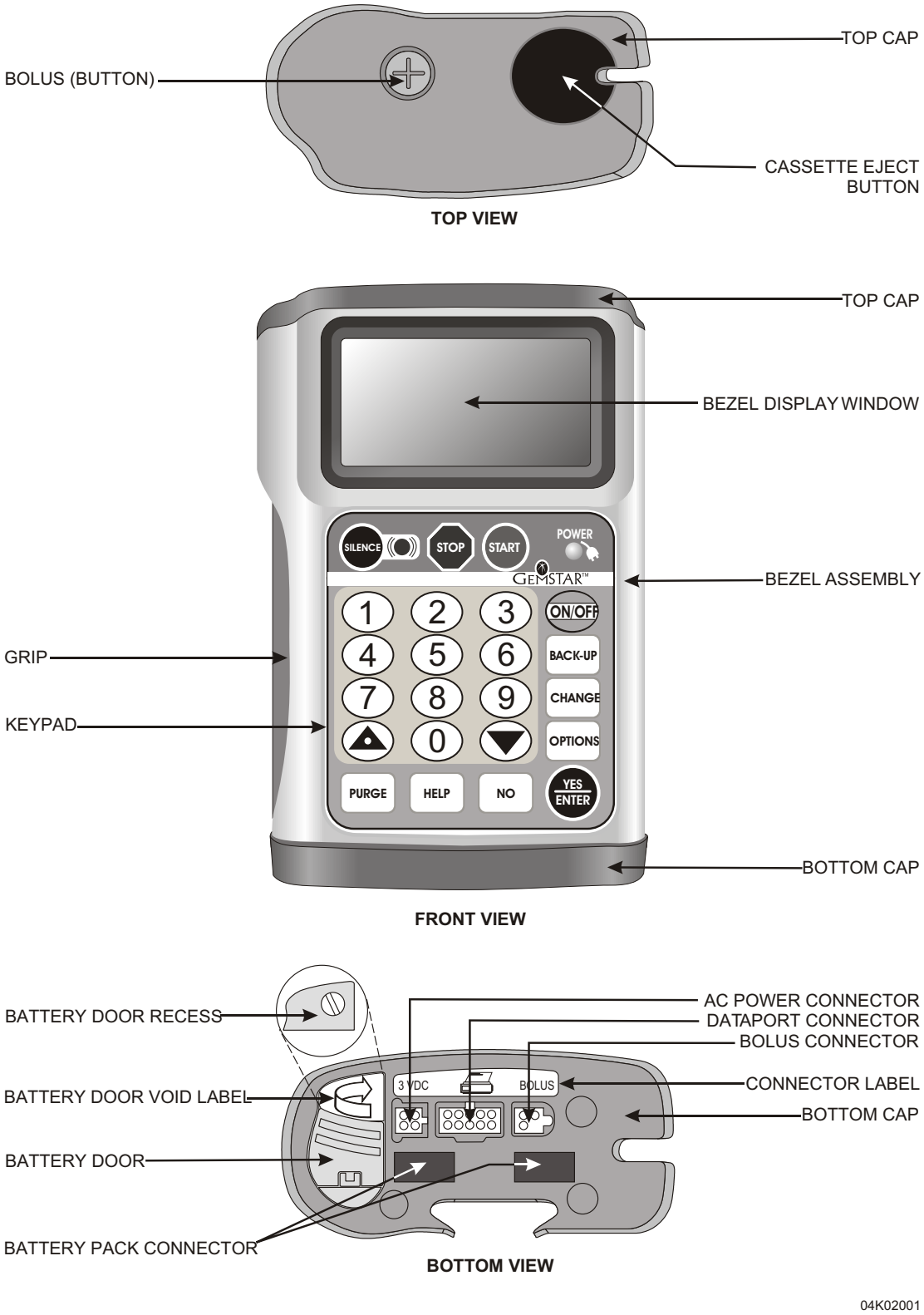

Figure 1-1. Illustration of the Infuser

Section 2

WARRANTY

Subject to the terms and conditions herein, Hospira, Inc., herein referred to as Hospira, warrants that the product shall conform to Hospira's standard specifications and be free from defects in material and workmanship under normal use and service for a period of one year after purchase. Hospira makes no other warranties, express or implied, as to merchantability, fitness for a particular purpose, or any other matter.

Purchaser's exclusive remedy shall be, at Hospira's option, the repair or replacement of the product. In no event shall Hospira's liability arising out of any cause whatsoever (whether such cause be based in contract, negligence, strict liability, other tort, or otherwise) exceed the price of such product, and in no event shall Hospira be liable for incidental, consequential, or special damages or losses or for lost business, revenues, or profits. Warranty product returned to Hospira must be properly packaged and sent freight prepaid.

The foregoing warranty shall be void in the event the product has been misused, damaged, altered, or used other than in accordance with product manuals so as, in Hospira's judgment, to affect its stability or reliability, or in the event the serial or lot number has been altered, effaced, or removed.

The foregoing warranty shall also be void in the event any person, including the Purchaser, performs or attempts to perform any major repair or other service on the product without having been trained by an authorized representative of Hospira and using Hospira documentation and approved spare parts. For purposes of the preceding sentence, “major repair or other service” means any repair or service other than the replacement of accessory items such as batteries, flow detectors, detachable AC power cords, and patient pendants.

In providing any parts for repair or service of the product, Hospira shall have no responsibility or liability for the actions or inactions of the person performing such repair or service, regardless of whether such person has been trained to perform such repair or service. It is understood and acknowledged that any person other than a Hospira representative performing repair or service is not an authorized agent of Hospira.

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Section 3

SYSTEM OPERATING MANUAL

A copy of the system operating manual is included with every GemStar infuser. Insert a copy here for convenient reference. If a copy of the system operating manual is not available, *contact Hospira (see Section 6.1, Technical Assistance)*.

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Section 4

THEORY OF OPERATION

This section describes the theory of operation for the GemStar. The theory of operation details the electro-mechanical and cassette systems. Related drawings are provided in *Section 9*.

4.1 ELECTRO-MECHANICAL SYSTEMS

The following sections describe the functions and electronic circuitry of the infuser.

4.1.1 CPU SYSTEM

The central processing unit (CPU) system consists of the following components:

- ❏ CPU: controls infuser operation
- ❏ Memory
  - RAM: stores temporary therapy program data; stores ROM program during software updates
  - ROM: stores the operating program
- ❏ Field programmable gate array (FPGA): provides auxiliary logic functions to operate the infuser

See *Figure 4-1, GemStar Block Diagram,* and *Figure 4-2, Board Connector References*.

4.1.1.1 CPU

The CPU (U2) is a Motorola MC68L11K1 8-bit processor powered by 3.3 V_{DC}. It operates at 2 MHz using a self-contained buffer and crystal Y1. The clock is divided by four to provide a 500 kHz bus clock (E-clock). Capacitors C9 and C11 provide the proper loading of the crystal.

The CPU provides the following:

- Separate data, address, and extended address lines
- On-chip 8-channel, 8-bit analog-to-digital converter
- On-chip EEPROM for non-volatile configuration status
- Non-maskable and maskable interrupt inputs
- Serial UART port
- Serial peripheral port
- 4-channel, 8-bit pulse-width modulated output
- General purpose input and output lines (I/O)

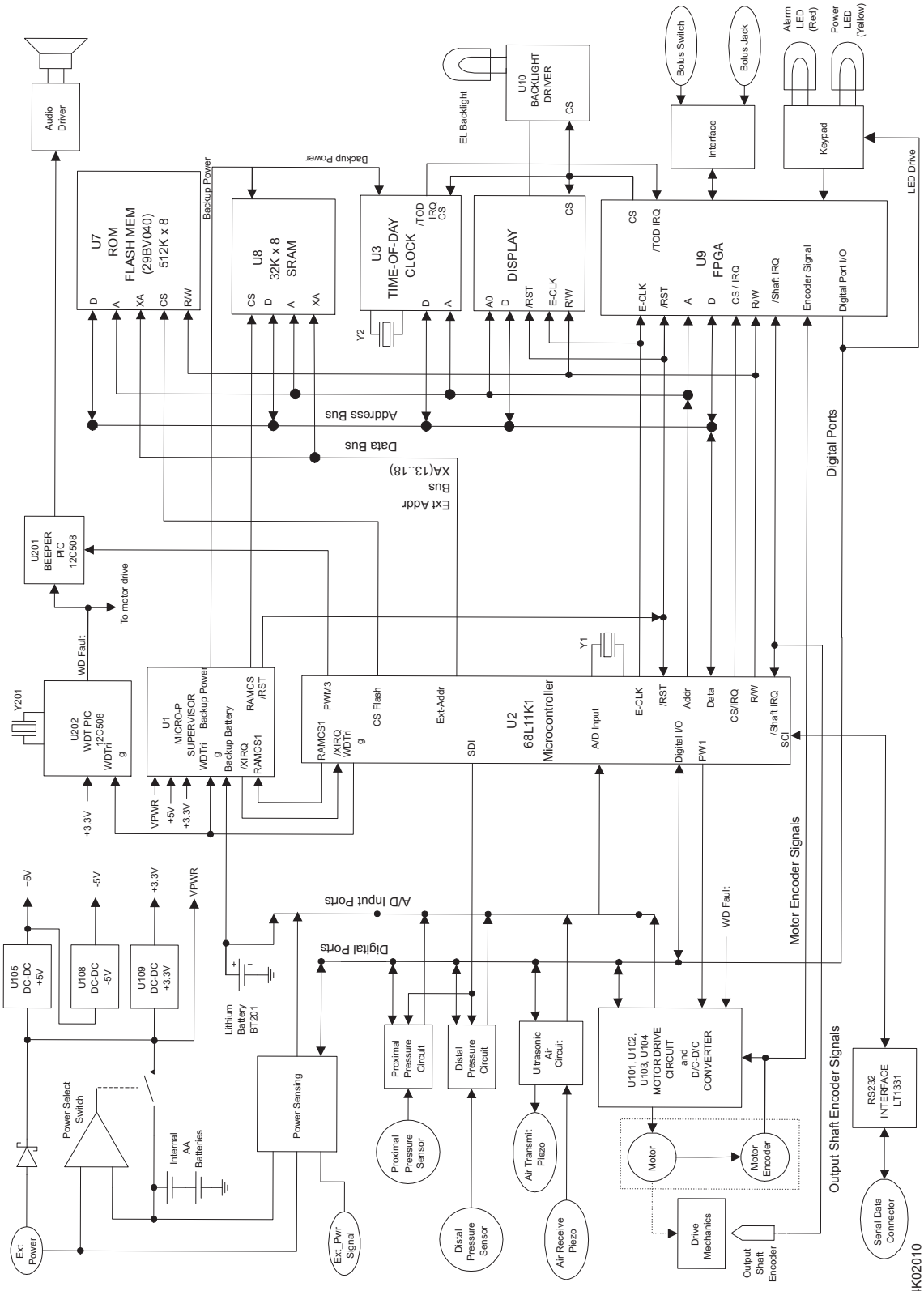

Figure 4-1. GemStar Block Diagram

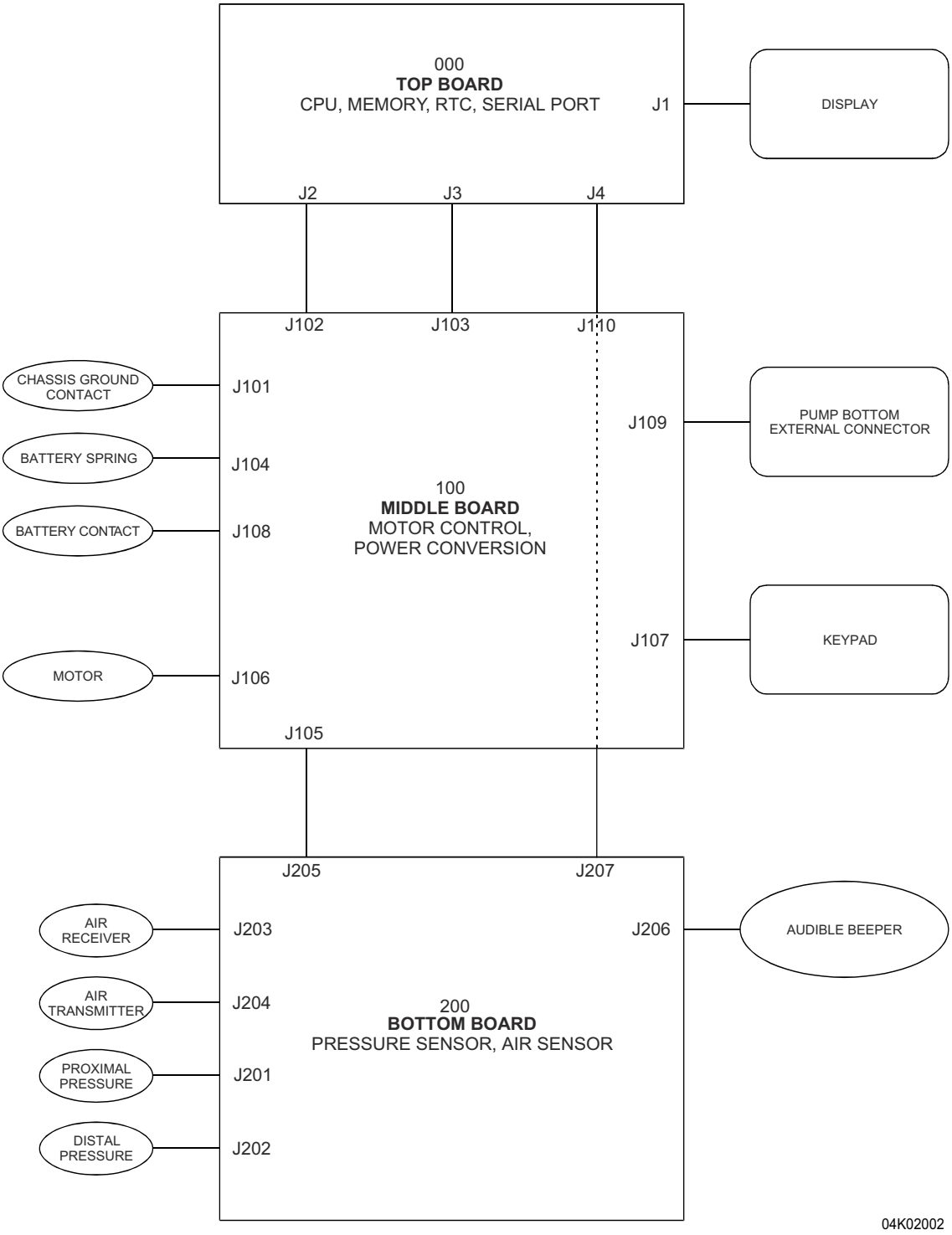

Figure 4-2. Board Connector References

4.1.1.2
MEMORY

The operating program is stored in a 512K x 8 flash ROM (U7) that can be reprogrammed with software updates.

Note: The program cannot be modified without special tools and protocols.

A 32K x 8 low-power static RAM (U8) is used to store the following data:

- Specific patient delivery protocols
- User options
- History records
- Operating program during Flash ROM programming

When the infuser is powered off, an on-board lithium battery provides power to the RAM chip.

4.1.1.3
FPGA

The FPGA (U9) is a specially programmed IC that incorporates auxiliary logic for the infuser. The FPGA provides the following:

- Input/output mapping
- Keypad interface
- Buffering and control of interrupt signals
- Additional logic interfaces for the infuser
- Motor encoder logic

The FPGA interfaces to the CPU through the address and data bus.

4.1.2
CPU SUPERVISORY FUNCTIONS

A MAX793R supervisory IC (U1) provides a secondary check for proper CPU functioning and monitors the following:

- Primary power source (V_{PWR})
- 3.3 volt power supply (V_{CC})
- Battery backup switch over
- Power-on and brownout reset

4.1.2.1
SUPPLY MONITORING

Whenever the 3.3 V power supply (V_{CC}) drops below a safe system operating voltage of 2.6 V_{DC}, U1 generates a system reset (/RST) that stops the computer and forces the watchdog circuitry to sound an alarm. U1 also monitors the primary power (V_{PWR}) and provides early detection of loss of primary power to the infuser. If V_{PWR} drops below the power fail input (PFI) voltage of approximately 1.3 V_{DC}, imminent loss of 3.3 V_{CC} power can be expected. When this happens, U1 interrupts program execution with a non-maskable interrupt via signal /PFO. This interrupt signals the microprocessor to execute a power-down routine that gracefully stops the motor, saves current data, and powers off the infuser.

4.1.2.2
POWER-ON RESET

During power-on or other reset conditions, the supervisory circuit holds the system in reset for 140 ms after V_{CC} reaches 2.6 V_{DC} to assure the system has stable power prior to starting normal operation. During reset conditions, the reset signal interfaces with all circuitry to assure conditions are held in a safe operational state (e.g., motor stopped).

4.1.2.3
MEMORY AND TIME RETENTION

Whenever all power sources are disconnected from the infuser, an internal 3.0 V lithium battery (BT201) provides power to retain memory and real-time clock operation. The lithium battery provides approximately three years of useful life as backup power from the time of infuser assembly. U1 monitors power, and whenever the supervisory circuit detects that the logic power is low (approximately 2.6 V_{DC}), it switches the lithium battery power to the appropriate circuits. A series 100 Ω resistor (R227) is used to measure the lithium current during off conditions. Voltage across R227 is normally less than 0.6 V_{DC} (6 μA).

4.1.2.4
WATCHDOG FUNCTION

U1 has a built-in secondary watchdog detection circuit (WDT) that provides a secondary check for proper CPU operation. The primary watchdog circuit is implemented using two programmable integrated circuit (PIC) microcontrollers on the bottom board (*see Section 4.1.2.6, WDT PIC/Beeper PIC/Beeper Driver*).

During normal operation, the CPU provides a one-second timing signal (WDTRIG) to the supervisory circuit indicating proper operation. If the WDTRIG signal is greater than approximately 1.6 seconds, the supervisory circuit will generate a system reset and stop all infuser operations.

Each of the following signals are driven low during system reset:

- Motor on (MOTORON)
- Motor drive enable (MOTDRVEN)
- Motor speed control (MOTSPCTL)

4.1.2.5
CPU ERROR CHECKING/WATCHDOG CIRCUITRY

The CPU is the primary error detection and checking component. When error conditions exist, the CPU generates an alarm, warning, or other action appropriate to the conditions. For example, it stops delivery when out-of-tolerance conditions are sensed.

The watchdog (U202) PIC has been designed to monitor the CPU for error-free operation. The CPU toggles the logic state of the watchdog trigger (WDTRIG). If the CPU becomes unstable, this signal will either not be generated or will have incorrect timing. The PIC processors monitor the WDTRIG signal for the correct timing. Whenever this signal is out of tolerance (1 sec ± 25%), U202 stops the motor (using the WDFLT signal) and sounds an alarm independent of the CPU.

4.1.2.6
WDT PIC/BEEPER PIC/BEEPER DRIVER

The watchdog WDT PIC (U202) is clocked from an external 32 kHz oscillator and crystal Y201 independent of the CPU clock. It monitors the WDTRIG signal for correct timing (change of state once a second). If either clock is in error or if the WDTRIG from the CPU is incorrect, the watchdog fault signal (WDFLT) goes low. This causes the beeper PIC (U201) to generate an audible alarm and the motor servo switching current source (U102) to stop the motor. When the infuser is turned off during normal power-down, the power-on (POWERON) signal from the CPU inhibits a WDTRIG fault while the power supply supercap discharges.

The beeper PIC (U201) can sound the beeper from the following two independent sources:

- Watchdog fault (WDFLT) signal from the WDT PIC (U202)
- Beeper control signal (BEEPCTL) from the CPU (U2)

When there is a watchdog fault, the WDFLT signal is activated and has the highest priority. When this happens, the motor turns off and the infuser stops. This causes the beeper PIC to produce an audible tone every five seconds.

The beeper PIC uses an internal 4 MHz oscillator and generates a predefined frequency and duty cycle for WDFLT faults. The CPU sends the BEEPCTL signal to generate audio output, such as audible operator alarms or keypad feedback. The beeper PIC passes the BEEPCTL signal frequency and duty cycle to the beeper. This allows different tones, duration, and volumes.

If the 3.3 V_{CC} supply drops below the minimum PIC operating level of 2.5 V_{DC}, the PIC CPUs are reset. R201, R202, R203, D204, and Q203 (brownout detector) provide a reset-generator, which nominally trips at 2.1 V_{DC}.

When power losses occur, such as an accidental disconnection of the AC adapter with no battery backup, two .047 F capacitors (supercaps) maintain the 3.3 V supply for approximately 10 seconds. This allows the CPU to execute an orderly shutdown, and provides enough power to the watchdog circuit to sound an audible alarm every five seconds after power loss (at least three audible beeps).

4.1.3
DISPLAY MODULE/BACKLIGHT

The display module is a 64-by-128 dot matrix LCD array with control and memory circuitry. The CPU and FPGA generate the display control signals. Since the display consumes only 1 mA, it is powered from a logic gate (U4A) that goes low when powered off. This allows the display to clear within seconds after power-off.

✎ **Note:** Display contrast can be factory adjusted.

An electroluminescent (EL) backlight illuminates the display. The CPU turns on the backlight drive circuit (U10) when a key is pressed or when AC mains power is applied.

4.1.4
KEYPAD/LEDS

A 23-key keypad receives operator input. One of these keys is used for power on/off (*see Section 4.1.9, Infuser On/Off Control*). Each of the other keys is at a distinct junction of an array of four columns and six rows, strobed by the FPGA approximately every 30 milliseconds. Pressing a key connects a row to a column. As the FPGA energizes each row, the columns are monitored and the FPGA determines which key has been pressed. A software routine eliminates noise (debounce) when the keys are pressed.

Two signal LEDs are mounted on the keypad and driven under software control, via FPGA outputs. The yellow LED illuminates when AC mains power is connected to the infuser. The red LED illuminates during an alarm condition, and is accompanied by an audible alarm and a display message, when applicable.

4.1.5
BOLUS SWITCHES

Patients can request a bolus dose for pain management and variable time protocols. The bolus switch (SW101) is located on the top of the infuser and is protected by a rubber end cap. The bolus switch signal (logic low) is buffered, inverted (U4C), and passed to the FPGA (U9-11) as the bolus request (BOLUSREQ) signal. The bolus request is latched by the FPGA and passed to the CPU as an interrupt.

An external (remote) bolus pendant can be connected to the bolus connector on the bottom of the infuser. The remote bolus pendant is wired in parallel with SW101. There is no distinction between the infuser bolus switch and the remote bolus switch. The buffering provided for the bolus request signal (U4C) allows for electrostatic discharge (ESD) rejection.

4.1.6
TIME-OF-DAY CLOCK

The infuser has a separate time-of-day clock (U3). The time is displayed at power-on and can be reset by the operator. This clock is used to provide the following:

- Schedule deliveries
- Record infuser history and event timing
- Generate a precise one-second CPU interrupt for timing functions

The internal lithium battery (BT201) powers the clock when no other power source is present.

4.1.7
POWER INPUT SENSING/SELECTION CIRCUITRY

The infuser can be powered by two internal disposable AA batteries, or an external power source connected to the 3.3 V connector on the bottom of the infuser (*see Figure 4-3, Power Input*). Power is applied to the internal voltage-power (V_{PWR}) line, which is connected or disconnected when the infuser is powered on or off (*see Section 4.1.9*).

Battery power connects to V_{PWR} through a fuse (F101) and a field effect transistor (FET) switch (Q110 A and B) controlled by comparator U110. The FET switch has an intrinsic forward diode, which allows sufficient battery current for the infuser to power-on when only batteries are present.

External power (EXTPWR) connects to V_{PWR} through an isolation diode D106. Comparator U110 senses the external voltage and automatically switches to external power when the external voltage (EXTPWR) is greater than approximately 1.8 V. When this happens, transistors Q106 and Q104 turn off the FET switch (Q110 A and B) to disconnect the internal batteries. The MAX965 (U110) has its own internal reference voltage at U110-6 of 1.235 V, which it uses to measure the switching point.

The external supply source may be from a DC supply connected to AC mains power or from an external battery. If the source is derived from AC mains power, a separate signal line is pulled high (to 3 volts). On external battery power, the signal line is low. The CPU monitors this signal line through the multiplexer (U106-4) and the A/D converter. The CPU uses this information when monitoring the external voltage to display appropriate messages (e.g., ON BATTERIES; LOW BATTERIES) or to turn on the power LED. The CPU monitors power source voltages. The internal (battery) and external voltages are connected to the CPU A/D input port through the multiplexer, MUX U106 (U106-13 and U106-15).

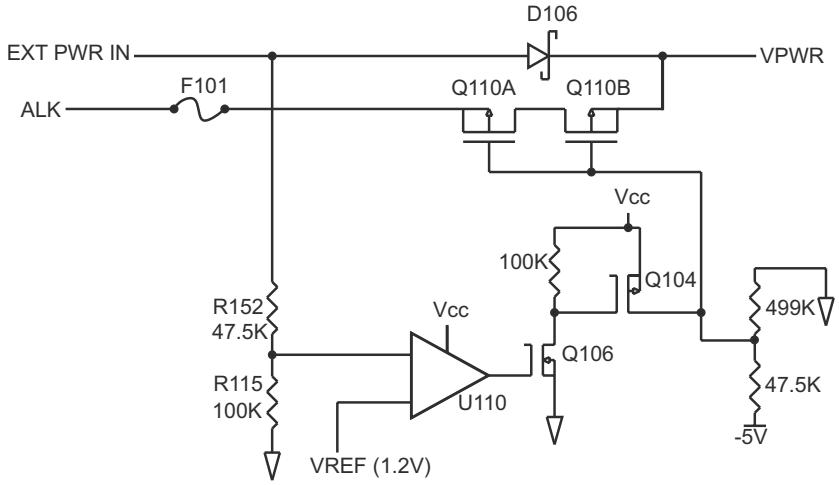

Figure 4-3. Power Input

4.1.8
INTERNAL POWER SUPPLIES

The input power at V_{PWR} is converted to three operating voltages: +3.3 V, +5 V, and –5 V.

The 3.3 V supply is U109, a ML4875-3 outputting 3.3 V on pin 5. This switch-mode regulator has internal FETs that ground inductor L103 and direct flyback current to the output capacitor (C140). The value of coil L103 is chosen to optimize input power to achieve 3.3 V_{CC} output power during high loads, such as high motor torque, sensors on, or backlight activated.

The +5 V supply is U105, a ML4875-5. This circuit is similar to the 3.3 V regulator, except for the output voltage. Both regulators have a tolerance of ± 3%.

The –5 V supply is U108, a MAX828 switched capacitor, +5 V to –5 V supply for high efficiency at low currents. The –5 V is required at various points to allow FETs to turn on with minimum resistance, which results in high efficiency and maximum battery life. A separate –5 V supply is used in the motor drive servo amplifier circuitry. U101, a second MAX828, provides –5 V to U103 A and B, and Q101.

The display backlight is an electroluminescent (EL) lamp that requires a symmetric, low-frequency alternating voltage. This voltage is generated by U10, a Durel™ D353 lamp driver IC. This IC uses inductor L1 in switch mode inverter circuit to drive the EL lamp.

4.1.9
INFUSER ON/OFF CONTROL

Electronic hardware and software, in conjunction with a dedicated ON/OFF button on the keypad, power the infuser on and off (*see Figure 4-4, Power On/Off Circuitry*). Flip-flop U107A, and the 3.3 V and 5 V supplies (U109 and U105), form the core of the electronic hardware. Pressing the keypad ON/OFF button grounds the on/off signal going to the on-off control circuit. The following two other control lines are also used:

- Shutdown signal (SHUTDOWN): a signal from the ON/OFF hardware to the CPU
- Power switch off signal (PWRSWOFF): a signal from the CPU to the ON/OFF circuit

These signals allow power to be turned on and off while preserving all data and assuring voltages are changed without damaging circuitry.

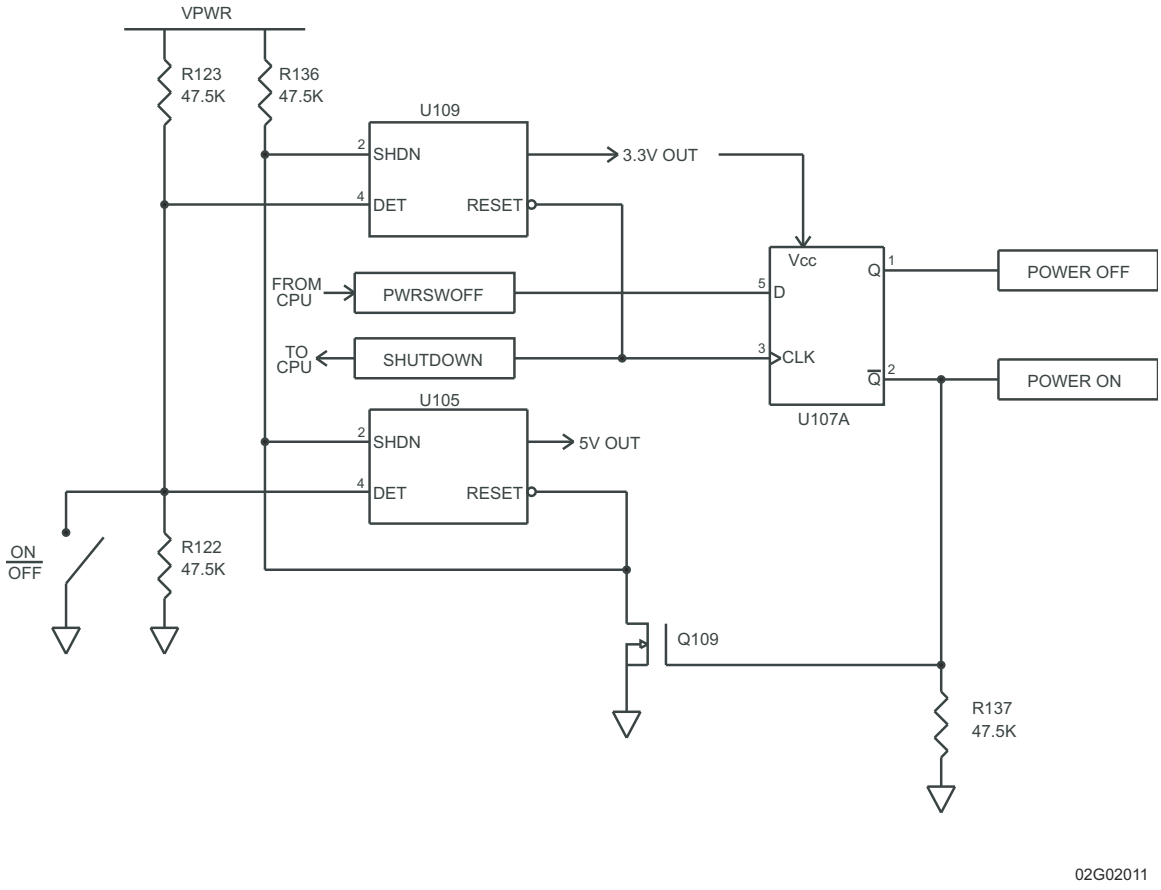

Figure 4-4. Power On/Off Circuitry

4.1.9.1
POWER ON

When power is first applied to the infuser, there is a voltage at V_{PWR}. However, the 3.3 V and 5 V supplies are held in a shutdown mode. The voltage at V_{PWR} is applied through resistor R136 to the shutdown inputs (U105-2 and U109-2). Meanwhile, the voltage at pin 4 of U105 and U109 (ON/OFF) is held at one-half V_{PWR} by resistor-divider R122 and R123. When the ON/OFF key is pressed, the on/off signal line is pulled low, which causes a comparator in U105-7 to go low and removes the shutdown signal on U105-4 and U109-4. These switching regulators rapidly change their outputs (VOUT on pin 5) to 5 V and 3.3 V respectively. This supplies power to flip-flop U107A where the clock is held low by the reset output of U109-7. When the ON/OFF switch is released, the ON/OFF line returns to one-half V_{PWR} and the reset lines on U105-7 and U109-7 return high. This clock flip-flops U107A. The Q-Bar output (U107-2) toggles high, switching the signal line power-on (POWERON) high. It also turns on transistor Q109, which removes the shutdown signal from power supplies U105-2 and U109-2. Simultaneously, the Q output (U107-1) toggles low, switching POWEROFF low. As a result, power is established and maintained.

4.1.9.2
POWER OFF

Power is removed from the infuser under CPU control. When the ON/OFF switch is pressed, it pulls pin 4 of the 3.3 V supply (U109-4) to ground. This causes the reset pin (U109-7) to pull low and puts a low on the signal line SHUTDOWN\ to the CPU. When this signal is received, the CPU begins its power-down sequence. First, it assures that power-down is a viable choice. For example, if the infuser is in the delivery (RUN) mode, the device will not power-off and a warning message will display. If power-down is a viable choice, the CPU gracefully shuts down by saving data, history, and other required housekeeping. When this is complete, the CPU changes the PWRSWOFF signal high. The ON/OFF switch must be pressed and held during this process, which may take up to three seconds. After the PWRSWOFF signal is switched high, releasing the power switch will change the signal ON/OFF and U109-4 back to one-half V_{PWR}. This will raise the signal at U109-7 and at the clock input of U107-A-3. The high on PWRSWOFF at the flip-flop data input U107A-5 will be clocked to the Q output, and the Q output will go high. At the same time, Q-bar (U107-2) will go low and Q109 will shut down both U109 and U105. This removes power from the circuits.

4.1.10
MOTOR DRIVE CIRCUITS

A high efficiency moving coil permanent magnet DC motor operates a plunger to deliver fluid. The motor includes a 27:1 speed reduction transmission and an integral, dual-channel, quadrature-encoded tachometer. The speed of the motor is set by the CPU. A hardware servo control circuit maintains the selected speed while compensating for variations in load torque, motor losses, and power source voltage. The CPU monitors the servo circuit by reading the motor voltage, motor current, and motor turns (encoder counts). The CPU also monitors the activation of the cassette (via output shaft encoder) to verify that motor turns are correctly converted into fluid delivery actions. See *Figure 4-5, Motor Control Circuit*, and *Figure 4-6, Detail of Motor Circuit*.

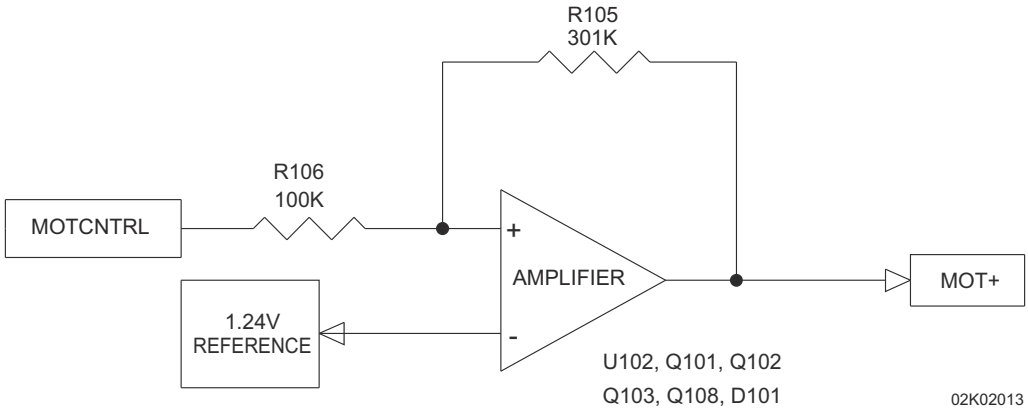

Figure 4-5. Motor Control Circuit

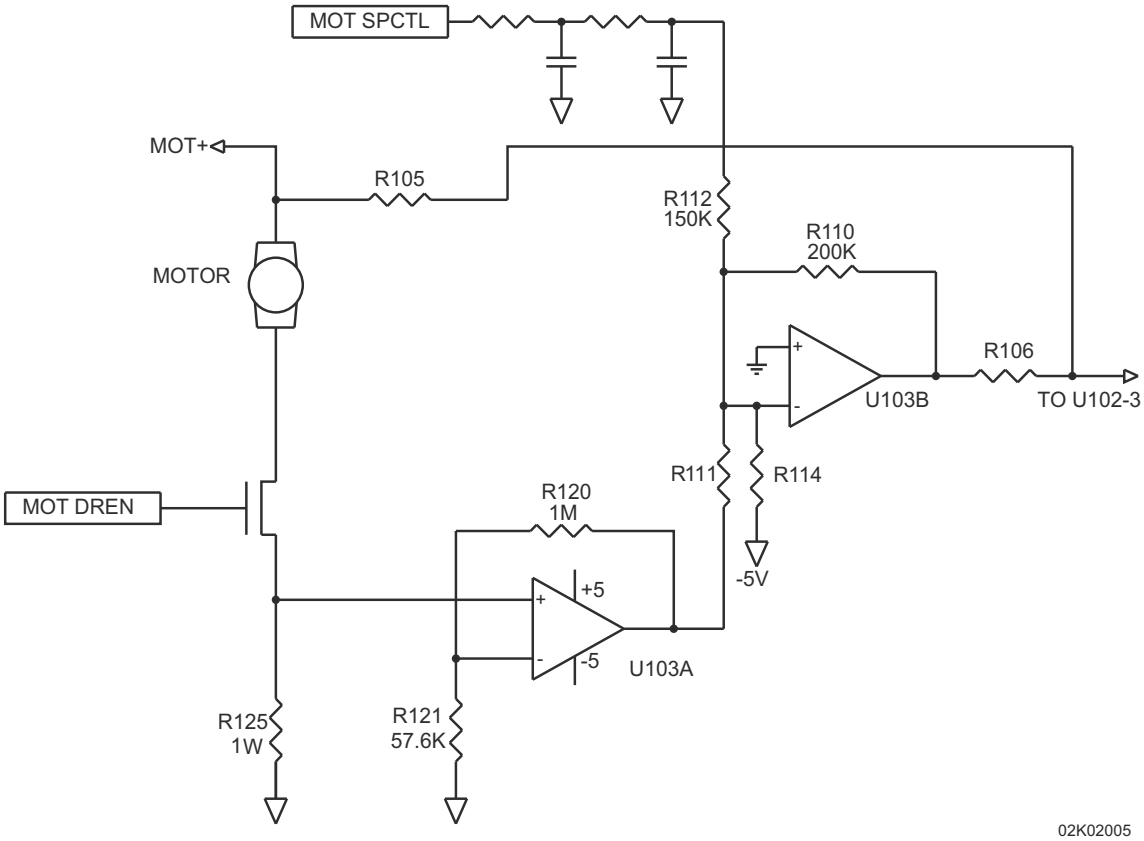

Figure 4-6. Detail of Motor Circuit

4.1.10.1

SPEED CONTROL

The CPU sets a desired speed. A summing amplifier (U103B) combines this speed setting, the motor speed (voltage across the motor), and the motor load (current through the motor) to establish a motor drive set point. This is converted into a drive voltage using a step-up DC-DC controller (U102). The CPU sets the motor speed as a pulse-width (duty-cycle) modulated signal (MOTSPCTL). Zero pulse width indicates a speed of zero, while full pulse width (100% duty cycle) is maximum speed resulting in approximately 1150 mL/hr delivery rate. A two pole RC filter (R117, C119, R118, C120) converts the duty cycle into a DC voltage (MSPEED). This voltage is fed to the summing amplifier U103B. Other inputs to this amplifier represent motor current and an offset reference current to assure the motor is off when the CPU sets a zero speed.

The motor current is sensed as the voltage across R125, amplified by U103A (gain approximately 18.4), and input to U103B via resistor R111. The motor current is sensed by the CPU A/D converter by monitoring the voltage at the output of U103A through R119 (MOTCUR).

The motor voltage and current range from approximately 1.5 V to 6.0 V, and 15 mA to 150 mA depending upon speed and load torque. This wide range of power must be delivered over the full range of input voltage (V_{PWR}) of 1.3 V to 3.2 V. To accomplish this, the motor servo output is a switch-mode up/down (buck/boost) voltage regulator (U102; Q108B; Q102 A and B; L102; D101; and D102). It receives a DC signal (MOTCNTRL) from the summing amplifier U103B and converts this to the required rate of current pulses to equal the necessary output power to the motor.

U102 is a step-up DC-DC controller that adjusts the output pulses at pin 1 to maintain a constant voltage of 1.24 V at the feedback pin 3. IC U102 and its associated switching circuitry may be considered part of high gain op-amp circuit with input resistor R106 and feedback resistor R105. The junction of R105 and R106, and U102-3 is a current summing point maintained by U102. The ratio of R105 to R106 sets the gain at –3. As the motor control signal (MOTCNTRL) at U103B-7 ranges from 1.65 V to –1.24 V, the motor voltage, MOT+, will range from zero to 8.68 V. If the voltage MOT+ at the right side of R105 begins to dip, U102-3 will dip, causing the output, U102-1, to output more control pulses. These are amplified, and become higher output DC after filtering. Individual components have been selected to make the servo circuit operate properly. U102 does not provide enough current, or the required negative voltage, to drive Q108B efficiently, so Q103 and Q101 are used in the classic complementary CMOS output configuration. The low side of this totem pole combination is tied to minus 5 V (MD-5V). This reduces the switching time of the FETs and hence minimizes current consumption. L101 has been selected to deliver approximately 1 V at the maximum frequency of output pulses from U102.

Peak current in L101 (22 _H) must be limited, or coil saturation may adversely affect efficiency. Based on the voltage drop across R103 (0.05 Ω), U102 automatically terminates the coil charging ramps at 1.6 amperes.

4.1.10.2

POWER CONSERVATION

To conserve power, the 5 V supply is disconnected when the motor circuit is not operating. To activate the motor circuitry, the CPU switches the motor drive on signal (MOTDRVON) high. This is inverted by U104A, turns transistor Q105A on, and connects 5 V to the motor drive 5 V line (MD5V). When positive 5 V is available on MD5V, U101, a MAX828 voltage inverter, generates a -5 V (MD5V) for the negative rail of the op-amps and for FET switching.

4.1.10.3

MOTOR

The drive motor is a combined gear motor with integral quadrature tachometer. The gearbox following the motor divides the motor speed by 27.0. The motor speed constant is chosen such that with the maximum voltage available from the servo, the motor output shaft will turn at a speed sufficient to provide approximately 1000 mL/hr. The motor speed constant is 0.75 V_{DC} per 1000 RPM. The mechanism converts rotary revolutions to in-out strokes for the cassette. One revolution equals one stroke to cassette.

The motor resistance is 15 Ω +/- 8% (16.2 Ω maximum). At 120 mA, the motor voltage loss may be as high as 15.1 x 0.12 = 1.81 V_{DC}. This internal motor drop is automatically adjusted for by the servo to keep the motor speed constant. The servo adds this lost voltage to the applied voltage to the motor. A 1 Ω resistor in series with the low side of the motor provides for the required motor current sensing.

To get 1000 mL/hr requires 220 RPM at the output shaft. With a 27:1 gearbox, the motor is turning 6000 RPM. At 0.75 V/1000 RPM, the basic drive voltage is 4.5 V. The total maximum required drive voltage is then: 4.50 + 1.81 + 0.12 = 6.43 V.

4.1.10.4

TACHOMETER

A digital tachometer keeps precise track of motor rotations. The tachometer is integrally mounted on the motor, and has a two-channel output (PHASE A, PHASE B). Each channel uses a Hall-effect sensor to generate a digital square wave of 16 pulses for each revolution. The pulses on one channel follow the other by a one-fourth pulse. This quadrature phase shift allows the direction of motor movement to be detected. Counting the pulses is an indication of motor movement and is converted into volume delivered. Play in the mechanism may result in backward motor movement. The tachometer allows the CPU to keep track of this and correct for reverse motion.

4.1.10.5

REDUNDANT MOTOR CONTROL

Note that when the microcontroller detects an error or out of tolerance condition, it can inhibit motor motion with any one of three commands. A logic low on MOTORON, MOTDRVEN, or MOTSPCTL will stop the motor. All three being a logic low adds triple redundancy for overdelivery protection.

4.1.11
MOTOR TACHOMETER POWER CONSERVATION

The motor tachometer is used to monitor motor speed. To minimize power consumption, the motor tachometer (encoder) is turned off whenever the motor is not running. In addition, when the motor is running, the tachometer is strobed. This means that at fixed intervals, the tachometer output is read into the computer. When it is not being read, it uses less power.

The tachometer is turned on just before the motor is turned on and remains on a short time after the motor turns off. It is switched on by the motor enable control signal (MOTENCON) from the CPU which turns on transistor Q108A to supply power to the tachometer on the motor (TACHVCC). The tachometer uses Hall-effect devices that switch on rapidly. A second line from the CPU, motor enable strobe (MOTENSTB), is buffered by U104E to become the tachometer strobe signal (STRB). This enables the Hall-effect devices to output the PHASE A and PHASE B signals. The strobe sampling rate is 31.25 kHz. This is fast enough to assure that no tachometer signals are missed, yet slow enough to conserve power. There are 16 tachometer pulses generated on each channel when the motor makes one revolution. The motor gear box has a gear ratio of twenty seven to one (27:1). This makes the output shaft turn once for every 27 motor turns. The drive shaft operates the pumping plunger once per revolution. As a result, there are 432 (16 x 27) tachometer pulses per pumping stroke.

The tach operates at 5 V (TACHVCC). To reduce the output signals to the 3.3 V levels required by the CPU system, resistors R145, R146, R107, and R108 divide the PHASE A and PHASE B signals.

4.1.12
OUTPUT SHAFT ENCODER

The motor output shaft turns the drive mechanism which drives the pumping plunger. A flag is attached to the end of the drive mechanism. Monitoring this flag allows the three following functions:

- A positive indication that the mechanism is operating when the motor is operating
- An indicator when the pumping plunger is in the home (fully retracted) position
- An indication of pumping speed

The flag is monitored using a reflective optical encoder (U208). The encoder LED emits an infrared beam of light. When the encoder flag enters the beam, it reflects light back to a photo detector which generates an output signal (SHFTSIGNAL). This signal is squared up by two inverters (U4D and E) before being input to the FPGA (U9-57) as shaft encoder check (SHFTENCH).

When the signal transitions low to high, this event is latched by the FPGA, which presents it to the CPU as an interrupt. In responding to this interrupt, the CPU polls a memory-mapped location in the FPGA to determine which external event caused the interrupt.

To assure correct motor operation, the shaft encoder looks for the flag every 8.2 ms whenever the infuser is on. This assures that the motor is only running when it should be. Any unauthorized motor movement or missing motor movement will be detected. To minimize power consumption, the shaft encoder is enabled for only 140 µs for a 2 % duty cycle. The shaft-on (SHFT-ON) control signal is generated at the FPGA (U9-30), passes through connectors J3, J103, J105, and J205 to R224 and U208.

4.1.13
AIR-IN-LINE SENSING

The GemStar uses an ultrasonic air detection system. The mechanism holds a pulse generator on one side of the IV tubing and a receiver on the opposite side. If there is fluid inside the tubing, the sound pulse is conducted to the receiver and a strong signal results. Air in the tubing gives only a weak signal. The pulse generator (transmitter) and the receiver are made of piezo-electric crystals. These convert electrical energy into mechanical motion or mechanical motion into an electric signal. Sending an electrical pulse to a transmitting crystal generates an ultrasonic pulse. When the pulse is transmitted to the receiving crystal, the pulse energy acting on the crystal generates an electrical output signal. This signal is amplified, filtered, and converted into a digital signal for processing by the CPU.

When the cassette is inserted into the infuser, the transmit and receive crystals are clamped to opposite sides of the IV tubing. The transmit crystal is driven by U207 and connected to J204. The receive crystal is connected to amplifier U206 through J203. To check for air, the CPU first applies power to the ultrasonic circuits (AIRON) by turning Q204 on. This activates power to the ultrasonic transmitter and receiver. After the U5V supply is stable (about 10 μs), and before transmitting, the CPU measures the receive signal to establish background noise levels. Next, a signal is transmitted. The signal toggle air (TOGLAIR) switches from low to high. This is buffered by U207D and causes one side of the transmit piezo to receive an out-of-phase signal from the other. The piezo deflects, and rings slightly to generate approximately a 700 kHz burst. Approximately 12 ms later, TOGLAIR returns to low. This causes the crystal to transmit a second signal. The CPU measures the AIR reading immediately after this transmitted pulse.

The receiver is a differential amplifier, U206, which rejects low frequency interference, such as 50-60 Hz, and triples the received signal. Inter-stage capacitor C219 is a high-pass filter that rejects frequencies up to approximately 100 kHz. The second-stage amplifier is Q205 with an AC gain of approximately 14. L20 and C215 tune the amplifier frequency response to optimize only the range of piezo ringing frequencies. Total AC gain is approximately 45. The amplified output is rectified and filtered by D201 and C206 and converted to a digital value by the CPU's A/D. The CPU records the signal value and the baseline values to determine whether air is present.

4.1.14
PROXIMAL PRESSURE MEASUREMENT

Proximal and distal pressures in the set are obtained by using strain gauges to measure forces on pins that contact the cassette diaphragm. The proximal pressure sensor pin contacts the cassette diaphragm at the inlet chamber. When proximal pressure decreases, the chamber deflates slightly and as a result, the pressure pin moves with the chamber wall. A resistive strain gauge connected to the pin deflects and changes its electrical output in proportion to the applied pressure. The signal from the strain gauge (J202) is filtered (R240; R241; C226; C227; C228) and then amplified by instrumentation amplifier U204 with a gain of 1000. Gain is established via gain resistor R211. The resultant signal, proximal pressure (PROXPRES), is converted to a digital signal by the analog-to-digital converter in the CPU (U2-48). The result is a signal with a range of 0 to 255. The normal proximal pressure range is from 2 psi to –8 psi. This pressure range results in a strain gauge signal change of approximately 1.75 mV_{DC}. The gain of U204 is 1000 and the ADC has full range reference voltage of 3.3 V (i.e., 3.3 V = 255 counts). As a result, the proximal pressure gauge has a range change of 135 counts (1.75 mV x 1000 x 255 counts/3.3 V).

Initial offset voltages of the strain gauge circuit are adjusted to zero during production test and calibration. During calibration, the CPU adjusts a digital potentiometer (U203) to cancel the offset voltage. The setting is stored as calibration data in the battery-backed-up RAM. The offset adjustment can be 6.75 mV.

4.1.15
DISTAL PRESSURE MEASUREMENT

The distal pressure measurement is very similar to the proximal. Rather than the pressure pin contacting the diaphragm directly, however, it contacts the cassette at the flow stop. The flow stop makes direct contact with the diaphragm. The opposite end of the pin contacts the strain gauge. The strain gauge connects at jack J201 and is filtered and amplified by U204 and the associated circuitry. Distal pressures are higher than proximal pressures (-5 to 40 psi). As a result, output voltages are larger (up to 6.75 mV) so the amplifier gain (U205) is smaller. Gain is set at 301 via gain resistor R212. The distal pressure gauge has a range change of 157 ADC counts (6.75 mV x 301 x 255 counts/3.3 V).

The distal pressure amplifier uses the same offset potentiometer that is used for proximal measurements. The CPU selects the appropriate value before taking a pressure reading. Because they share the same offset resistor, distal and proximal pressures cannot be measured at the same time.

To conserve power, the pressure measurement circuits are turned off between readings. The control signal from the CPU is called pressure sense on (PRSENSON). Transistors Q201 and Q202 connect + 5 V (5V-B) to the sensors (P5V) while transistors Q207 and Q208 connect - 5 V (-5 V-B) to the sensors (P-5V).

4.1.16
RS-232 INTERFACE SYSTEM

The infuser has an RS-232 interface to allow connection to a multiple of RS-232 devices. This allows printing reports, downloading new software, remote monitoring, and modem interfacing. The circuitry uses an RS-232 transceiver/receiver (U5) to buffer the signals. To input data, U5 receives the RS-232 logic level signals, serial data in [SDATIN] and serial control in [SCTLIN], converts them to 3.3 V_{DC} logic level signals, and connects to the CPU UART serial port. For output, U5 receives 3.3 V_{DC} logic level signals from the CPU UART serial data out (SDATOUT), and serial data control out (SCTLOUT) and converts them to RS-232 logic levels for external transmission from the infuser at J109.

U5 provides ohmic isolation between the infuser circuitry, and the RS-232 inputs and outputs. This isolation is good to several thousand volts, giving the infuser the ability to withstand electrostatic discharges on the serial port pins. When the serial port is not being used, the IC is switched to a low-power mode. The logic line serial-on (SERIALON) (U9-29) connects to U5-13, disables the charge pump, and switches the outputs to high-impedance output states.

4.2
CASSETTE SYSTEM

The GemStar cassette is a small, low cost, sterile pumping chamber that snaps into the infuser to deliver fluid to the patient. The cassette snaps and locks into the infuser without the need for a separate door. When the cassette release button on the top of the infuser is depressed, the cassette is released. When released, the cassette is automatically protected against fluid free-flow. By opening the flow stop rocker, the cassette may be gravity primed. The cassette has an infusion range from 0.1 mL/hr to 1000 mL/hr. Air is ultrasonically detected by the infuser in the tubing as fluid exits from the cassette.

A pumping chamber forms the heart of the cassette. It interfaces to a plunger in the infuser. When the plunger is depressed, fluid in the chamber is exhausted through a one-way outlet valve to a small outlet chamber. When the plunger is retracted, the outlet valve closes and a one-way inlet valve opens to let fluid in from a small inlet chamber. The volume pumped for each pumping cycle is approximately 75 microliters (about 13 strokes per mL). The inlet and outlet chambers connect to strain gauges in the infuser to monitor proximal and distal tubing pressures. A latching flow stop contacts the outlet chamber. When it is latched open, the outlet valve is free to open and close. When latched closed, it causes the outlet valve to remain in the closed position, preventing fluid flow when the cassette is outside of the infuser.

The cassette consists of four parts: body, top, diaphragm, and flow stop.

4.2.1
BODY AND TOP

The body and top enclose the silicone diaphragm to form the inlet, pumping, and outlet chambers. The flexible diaphragm mates to the body to enclose the chambers and form the one-way valves. The pump plunger presses on the diaphragm to empty the pumping chamber and when the plunger retracts, the spring force of the diaphragm refills the pumping chamber.

4.2.2
DIAPHRAGM

Fluid enters the cassette at the inlet port to fill the inlet chamber. The top of this chamber is part of the diaphragm. A pin from the infuser contacts the top of this chamber to detect any deflection. If pressure drops in this chamber (evidence of a proximal occlusion), the top of the chamber will deflect, which the infuser can sense. The infuser analyzes this deflection to determine if there is a proximal occlusion.

When the pump plunger retracts, fluid is drawn from the inlet chamber to the pumping chamber through the one-way flapper valve. When the plunger completes the retracting stroke, it reverses direction. The flapper valve to the inlet chamber closes. As the plunger advances, pressure builds in the pumping chamber and opens the outlet valve. Fluid moves to the outlet chamber and the outlet port to the patient.

Like the inlet chamber, the outlet chamber top is part of the flexible diaphragm. The flow stop contacts the diaphragm and a pin from the infuser contacts the flow stop. If pressure builds up in the outlet chamber (evidence of a distal occlusion), the top of the chamber will deflect, which the infuser can sense. The infuser analyzes this deflection to determine if there is a distal occlusion.

4.2.3
FLOW STOP

The flow stop is a rocker that latches either open or closed. When closed, it will deflect the top of the outlet chamber to press the outlet valve closed. The flow stop pressure is sufficient to prevent free-flow to about a nine-foot head height. After priming, a caregiver should close the flow stop prior to installing the cassette in the infuser. However, when the cassette is installed into the infuser, the flow stop is switched to the closed position automatically. As the plunger engages the chamber, it relaxes the outlet valve and reduces the valve cracking pressure. When the cassette is removed from the infuser, the flow stop remains in the closed position and requires manual opening for priming.

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Section 5

MAINTENANCE AND SERVICE TESTS

A complete maintenance program promotes longevity and trouble-free instrument operation. Such a program should include routine maintenance, periodic maintenance inspection, and performance verification testing.

This section details routine maintenance procedures and the performance verification test.

Note: Store the infuser in a cool, dry place. Remove the disposable batteries or optional battery pack before storing the infuser.

Note: Program and Event History are protected in memory for at least one year when power is removed from the infuser.

5.1 ROUTINE MAINTENANCE

Routine maintenance consists of basic inspection and cleaning procedures. As a minimum requirement, inspect and clean the infuser after each use. In addition, establish a regular cleaning schedule for the device.

The infuser's internal lithium battery has a useful life of three (3) years. The infuser must be returned to Hospira in order to replace the lithium battery. *Contact Hospira* to return the infuser for replacement of this battery.

5.1.1 CLEANING

Accumulation of dust or spilled fluids on the cassette door and housing can affect proper operation. The following cleaning procedures are designed to sustain longevity and promote trouble-free operation.

Follow hospital protocol for establishing the infuser cleaning schedule.

WARNING:	**DISCONNECT THE INFUSER FROM AC POWER AND REMOVE THE BATTERIES OR BATTERY PACK PRIOR TO CLEANING. FAILURE TO COMPLY WITH THIS WARNING COULD RESULT IN ELECTRICAL SHOCK.**

CAUTION: Do not immerse the infuser in liquids. Immersion could damage the device. Do not allow liquids to enter the electronics compartment. Do not spray cleaning solutions toward any openings in the device.

CAUTION: Certain cleaning and sanitizing compounds may slowly degrade components made from some plastic materials. Using abrasive cleaners or cleaning solutions not recommended by Hospira may result in product damage and, potentially, void the product warranty. Do not use compounds containing combinations of isopropyl alcohol and dimethyl benzyl ammonium chloride.

CAUTION: Clean the exposed surfaces of the infuser with a soft, lint-free cloth dampened with one of the cleaning solutions listed in *Table 5-1*, or a mild solution of soapy water. Remove soap residue with clear water. Do not use solvents that are harmful to plastic. Do not use abrasive cleaners.

CAUTION: To avoid damage to the device, cleaning solutions should be used only as directed in *Table 5-1*. The disinfecting properties of cleaning solutions vary; consult the manufacturer for specific information.

Table 5-1. Cleaning Solutions

Cleaning Solution	Manufacturer	Preparation
Coverage™ HB	Steris Corporation	Per manufacturer's recommendation
Dispatch™	Caltech Industries	Per manufacturer's recommendation
Manu-Klenz™	Steris Corporation	Per manufacturer's recommendation
Precise™	Caltech Industries	Per manufacturer's recommendation
Sporicidin™	Sporicidin International	Per manufacturer's recommendation
Household bleach	Various	Per hospital procedures; do not exceed one part bleach in ten parts water

5.1.1.1
SANITIZING

Sanitize the external surfaces of the infuser using a cleaning solution listed in *Table 5-1*.

Note: Not all cleaning solutions are sanitizers. Check product labeling.

CAUTION: Do not sterilize the infuser using heat, steam, ethylene oxide (ETO), or radiation. These methods may cause the instrument to malfunction.

5.1.1.2

CLEANING THE CASSETTE POCKET AND TUBING CHANNEL

Clean the cassette pocket and the tubing channel on a regular basis. The ultrasonic sensors are located in the cassette pocket.

CAUTION: Do not damage the silicone seals around the sensor bodies.

See *Figure 5-1, Cassette Pocket and Tubing Channel*, and complete the following steps:

1. Remove the cassette.
2. Using a cotton swab moistened with a recommended cleaning solution, clean the sensor faces (A), tubing channel (B), plunger tip (C), and sensor pins (D).
3. Dry the sensor faces and tubing channel and confirm that the sensor faces are free of detergent film and/or debris.

Note: Removing excess cleaning solution from the infuser helps prevent detergent buildup, which could adversely affect performance.

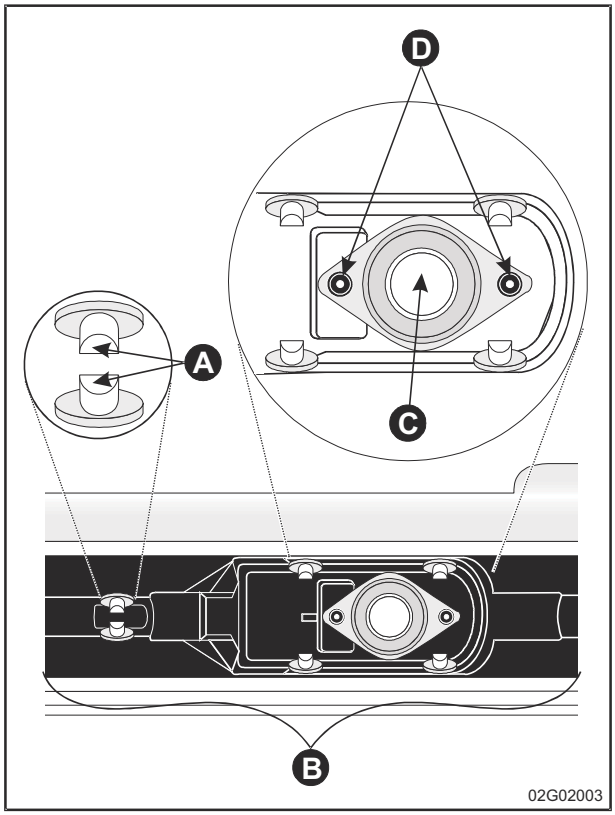


Figure 5-1. Cassette Pocket and Tubing Channel

5.1.2
INSPECTION

Inspect the infuser periodically for signs of defects, such as worn accessories or damaged cables. Also, inspect the infuser after repair or during cleaning. Replace any damaged or defective external parts.

The following sections detail infuser inspection procedures.

5.1.2.1
MATERIALS REQUIRED

Infuser inspection requires the following materials:

- Cotton swab
- Cleaning solution
- Infuser administration set
- Small flashlight
- Two fresh AA disposable batteries
- 3 V_{DC} AC adaptor (optional)
- Digital multimeter (DMM) (Optional)

5.1.2.2
LABEL INSPECTION

See *Figure 5-2, Label Inspection*, and verify the following labels are present and in good condition:

1 Hospira void label

2 Configuration letter label

3 System kit label

4 Serial number label

5 GemStar logo void label

6 Operating instructions label

7 Battery door void label

8 3 V_{DC}/printer/bolus connector label

9 Battery insertion label (not shown; located inside the battery compartment)

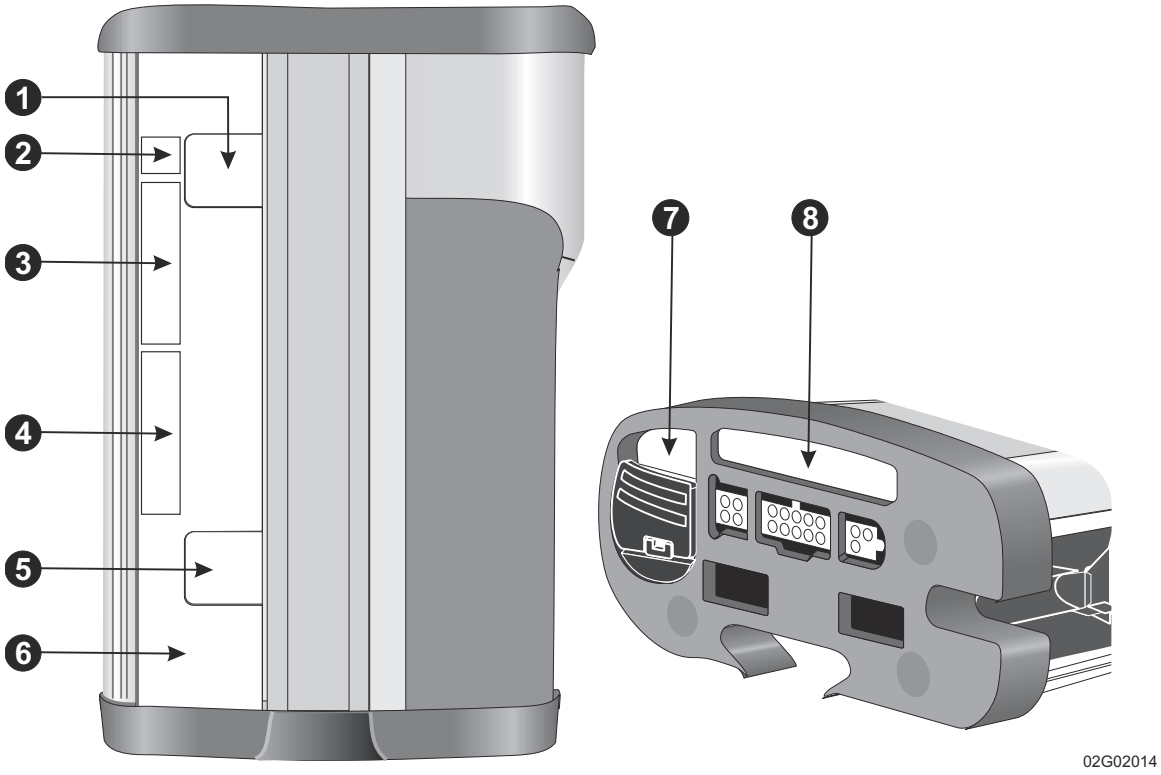


Figure 5-2. Label Inspection

5.1.2.3

LATCH MECHANISM INSPECTION

See *Figure 5-3, Cassette Retention and Ejection*, and complete the following steps:

1. Verify the four cassette latches are present.
2. Load a cassette into the chassis pocket and push the cassette until all four cassette latches securely hold the cassette in place.
3. Gently pull on the distal and proximal tubing to verify that the latches secure the cassette.
4. Push the cassette release button until the cassette snaps free from the service position.
5. Gently pull on the distal or proximal tubing to verify the cassette can be removed from the chassis with minimum resistance.

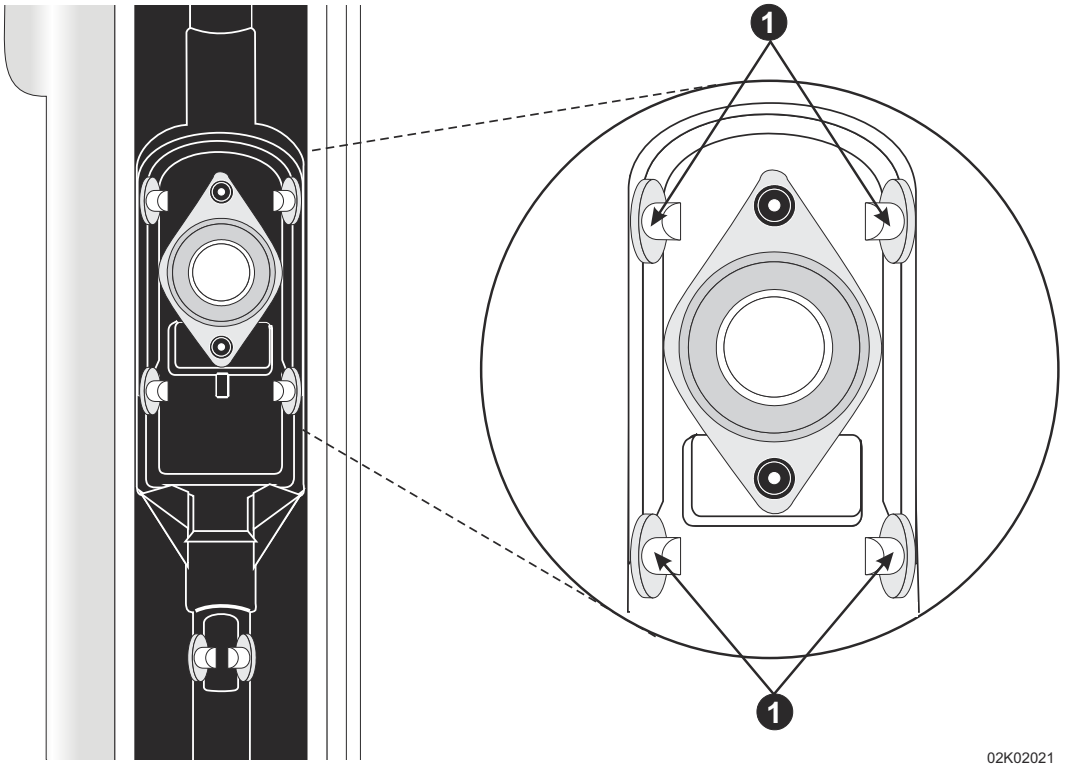


Figure 5-3. Cassette Retention and Ejection

5.1.2.4

AIR SENSOR INSPECTION

See *Figure 5-4, Air Sensor Inspection,* and complete the following steps:

1. Verify the two air sensor anvils are present and in good condition.
2. Apply gentle pressure to each anvil face with a cotton swab to verify the sensors retract and re-position.
3. Load the set into the chassis, nest the tubing between the air sensor anvils, and verify that both anvils engage the distal set tubing.
4. Verify the two sensor seals are present and in good condition. Each seal should be free of tears and nest snugly around the sensor. The seals should not interfere with contact between the anvil face and the set tubing.
5. Verify the sensor seal pockets and sensor anvils are free of debris and contamination.

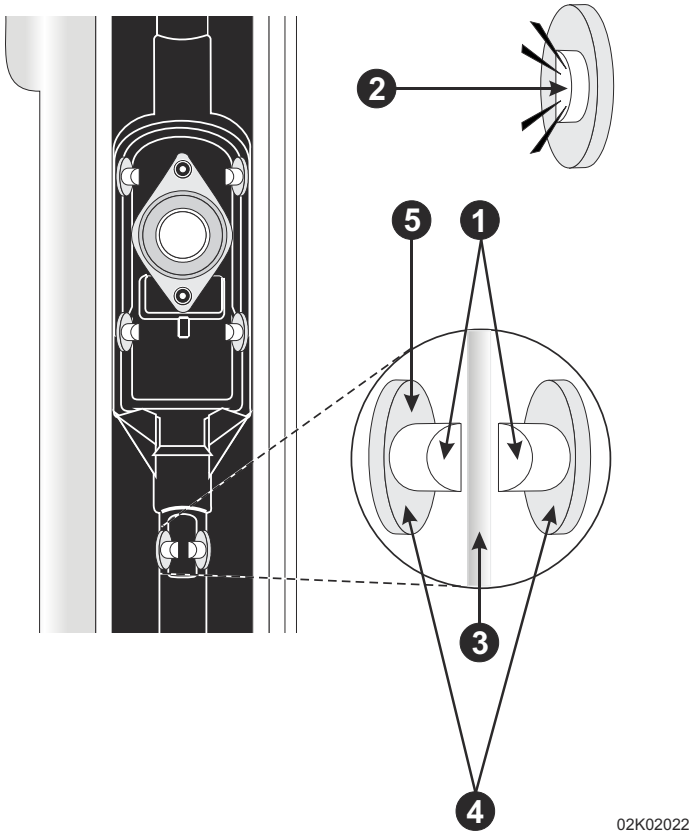


Figure 5-4. Air Sensor Inspection

5.1.2.5

PLUNGER AND PRESSURE SENSOR INSPECTION

CAUTION: DO NOT apply excessive force to pressure sensor pins. Excessive force may damage sensor pins or internal beams.

See *Figure 5-5, Plunger and Pressure Sensor Inspection,* and complete the following steps:

1. Verify the plunger seal is present and in good condition.
2. Apply gentle pressure to the plunger to verify transmission compliance. There should be no significant free-play or reversing of the plunger position.
3. Verify the two pressure sensor pins are present and in good condition.
4. Using one finger, apply gentle pressure to each pressure sensor pin to verify proper beam deflection. The pin should retract slightly then re-position after pressure is removed.

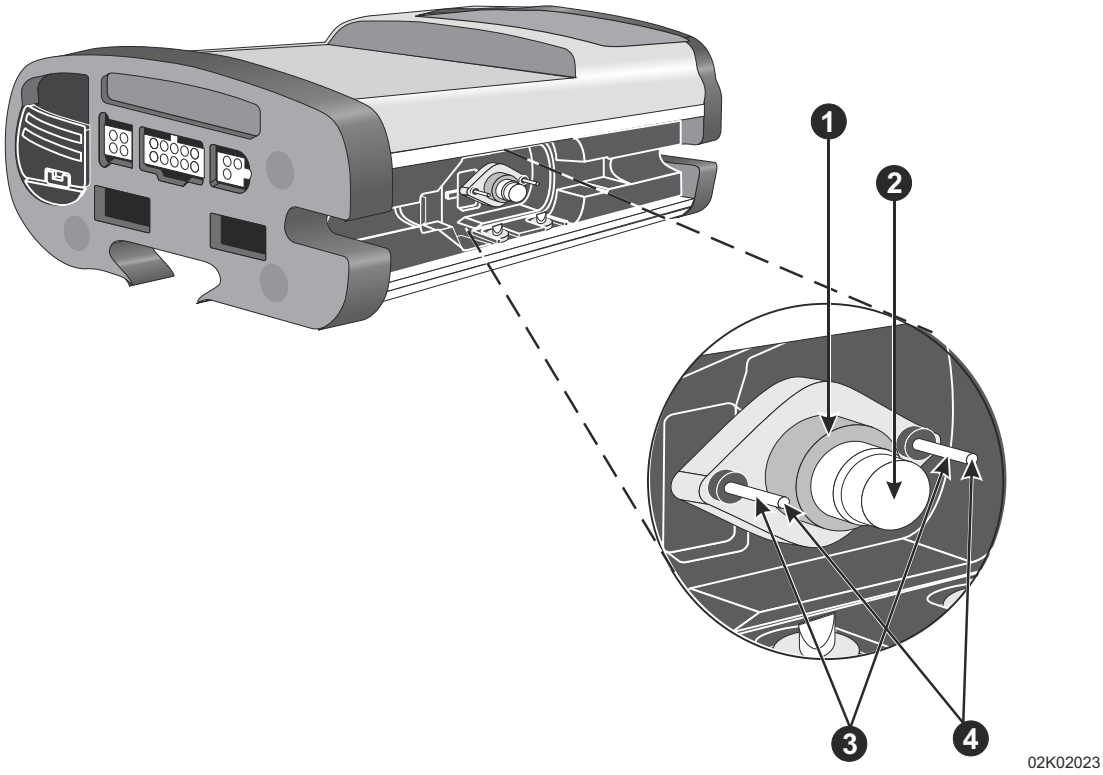


Figure 5-5. Plunger and Pressure Sensor Inspection

5.1.2.6

TOP CAP INSPECTION

See *Figure 5-6, Top Cap Inspection*, and complete the following steps:

1. Verify the top cap is free of cracks, holes, and evidence of fluid ingress.
2. Verify the seal between the top cap and the bezel/extrusion is present and in good condition.
3. Verify the condition of the pole clamp retainer.

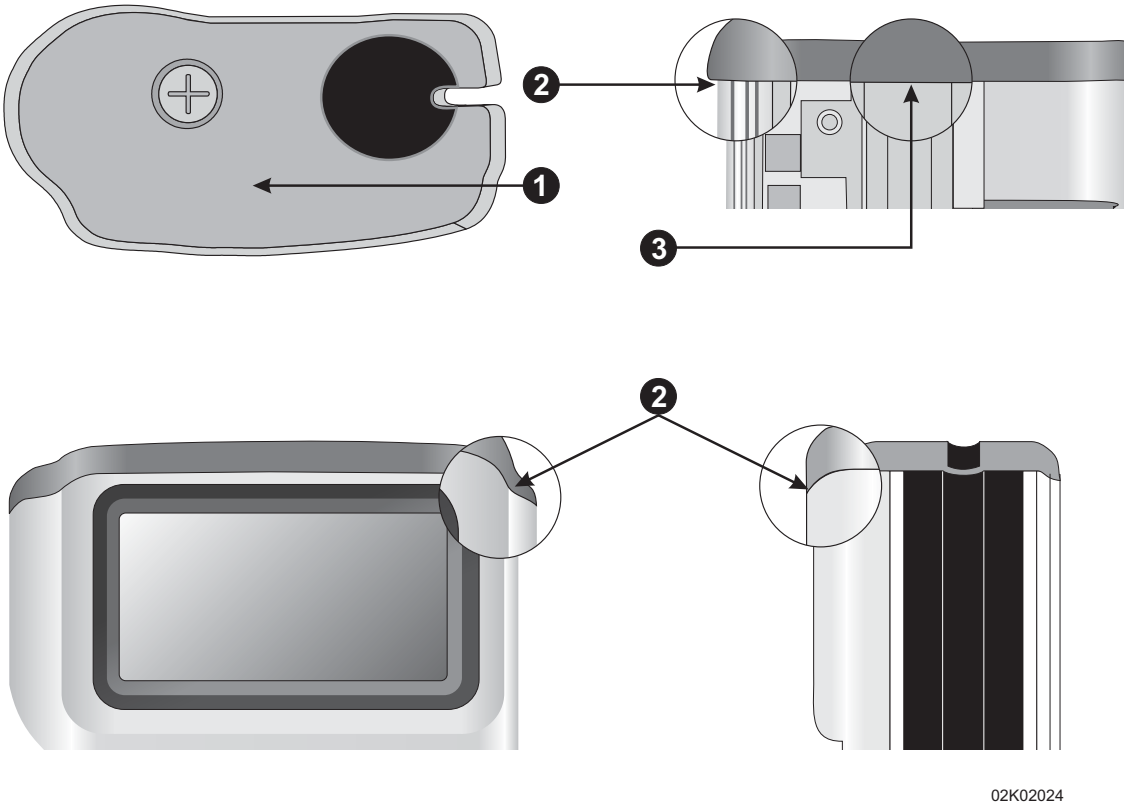


Figure 5-6. Top Cap Inspection

5.1.2.7
BOTTOM CAP INSPECTION

See *Figure 5-7, Bottom Cap Inspection*, and complete the following steps:

1. Verify the bottom cap is flush with the extrusion and bezel.
2. Verify the bottom cap is free of cracks and holes.
3. Verify all three hole plugs are present.

Note: Steps 4 through 6 apply to the GemStar with the optional system component interface.

4. Verify each port is free of foreign material and contamination.
5. Verify that each port retention and keying features are free from damage.
6. Verify that each gold contact is clearly visible, intact, and free of contamination.

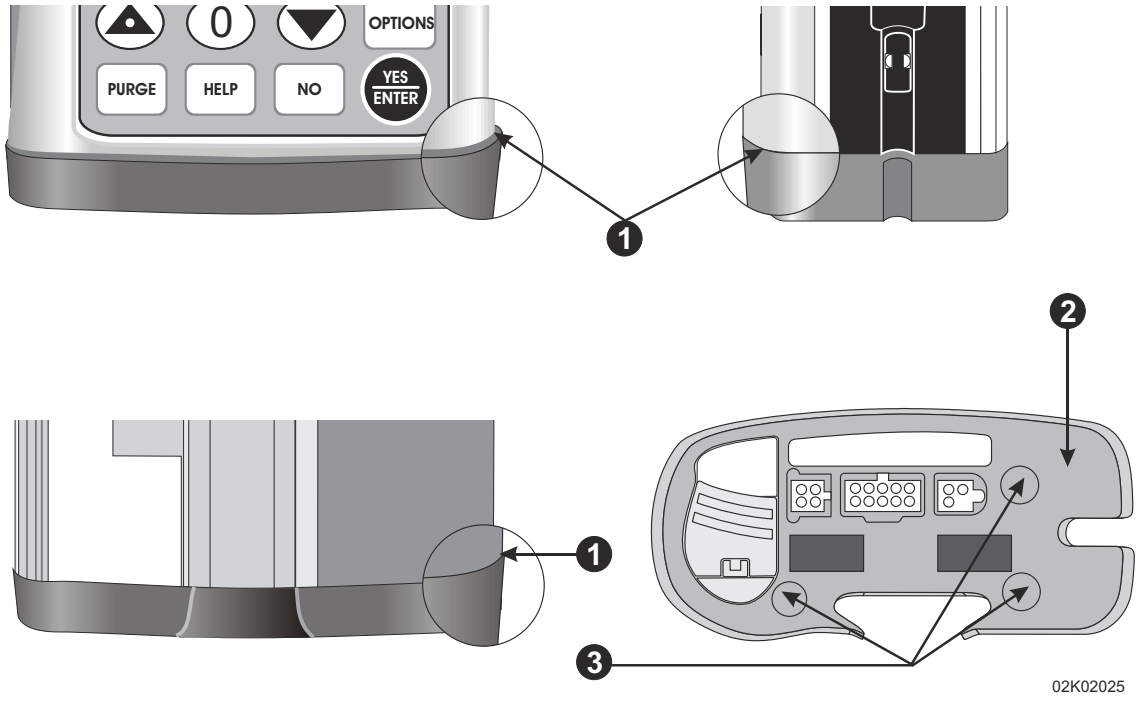


Figure 5-7. Bottom Cap Inspection

5.1.2.8

BEZEL, GRIP, AND KEYPAD INSPECTION

See *Figure 5-8, Bezel, Grip, and Keypad Inspection*, and complete the following steps:

1. Verify the bezel face is in good condition.
2. Verify the seal of the bezel face to the grip.
3. Verify the bezel tail is in good condition.
4. Verify the seal of the bezel tail to the grip.
5. Verify the seal of the bezel face edge to extrusion.
6. Verify the keypad is free of damage and that each key provides tactile feedback when pressed.

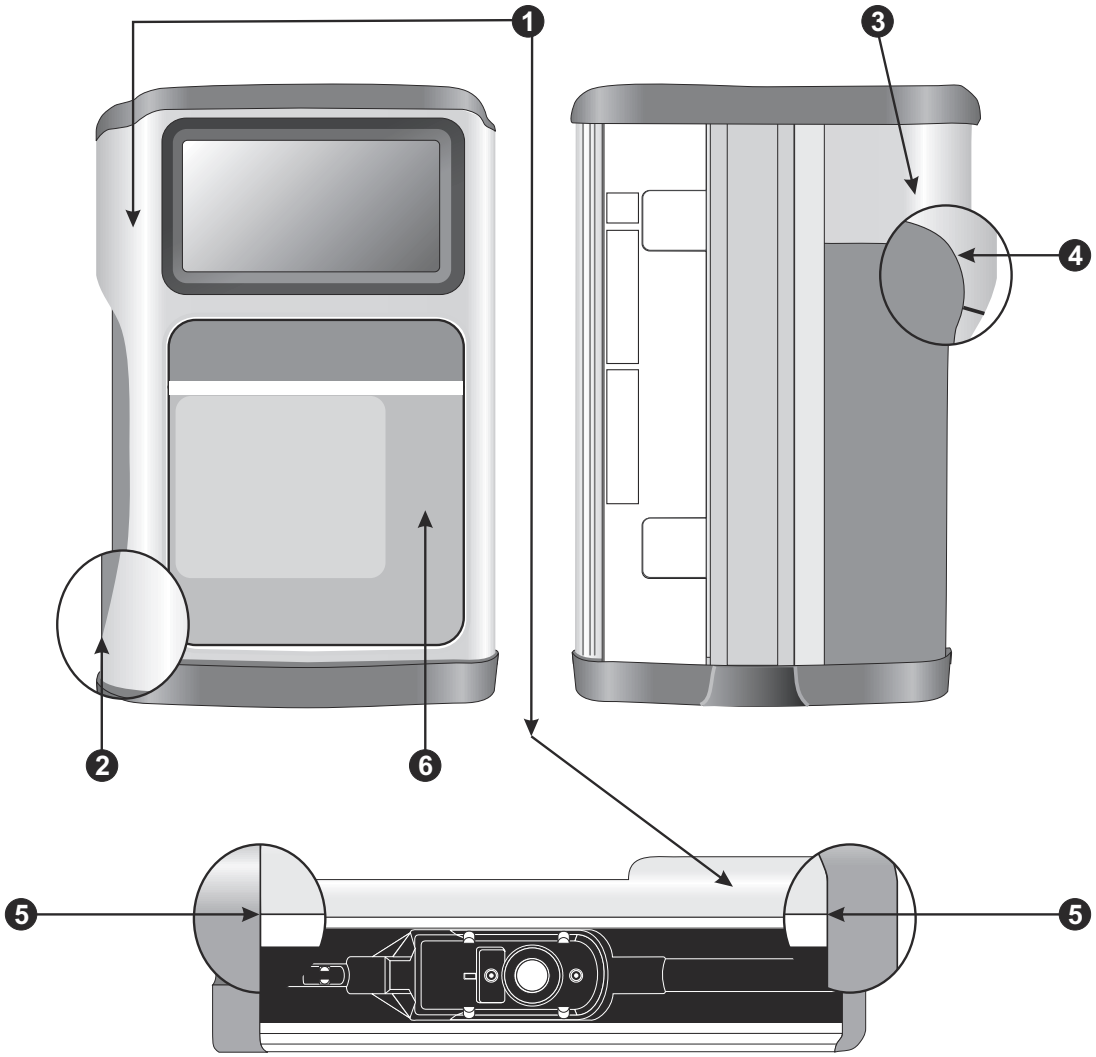


Figure 5-8. Bezel, Grip, and Keypad Inspection

5.1.2.9

BATTERY DOOR AND COMPARTMENT INSPECTION

The following sections describe battery door and battery compartment inspection.

5.1.2.9.1

Battery Door Engagement

See *Figure 5-9, Battery Door Engagement*, and complete the following steps:

1. Flip the door latch to the open position, then to the closed position, then to the open position again. The door latch should snap positively in both positions with no free-play.
2. Verify the door retainer is present and in good condition.
3. Gently rotate the battery door latch counterclockwise to the open position, then clockwise to the closed position to verify proper engagement. The door is properly engaged when the door is secured by the door retainer.

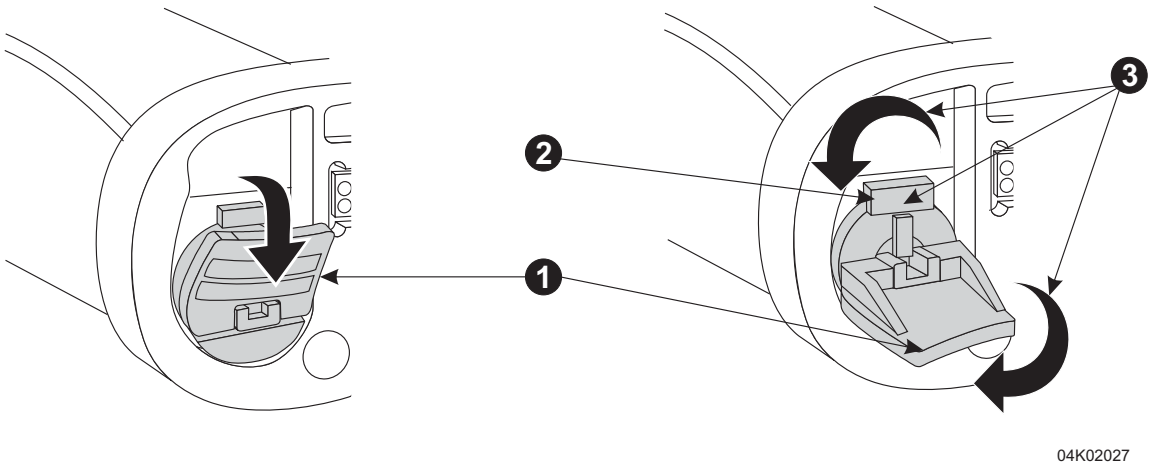


Figure 5-9. Battery Door Engagement

5.1.2.9.2

Battery Door Inspection

See *Figure 5-10, Battery Door Inspection*, and complete the following steps:

1. Remove the battery door from the infuser.
2. Verify the o-ring is present and in good condition.
3. Verify the door latch and plunger hinges are free of fractures.
4. Verify the spring is secure with no wobble or excessive collapse.
5. Verify the wiper contact is free of contamination, corrosion, and excessive deformation.

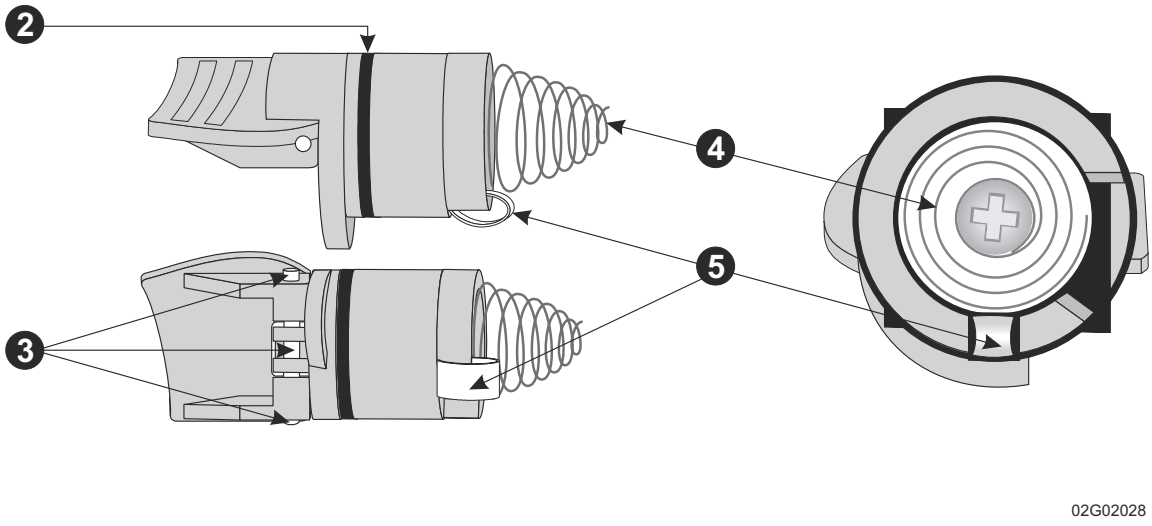


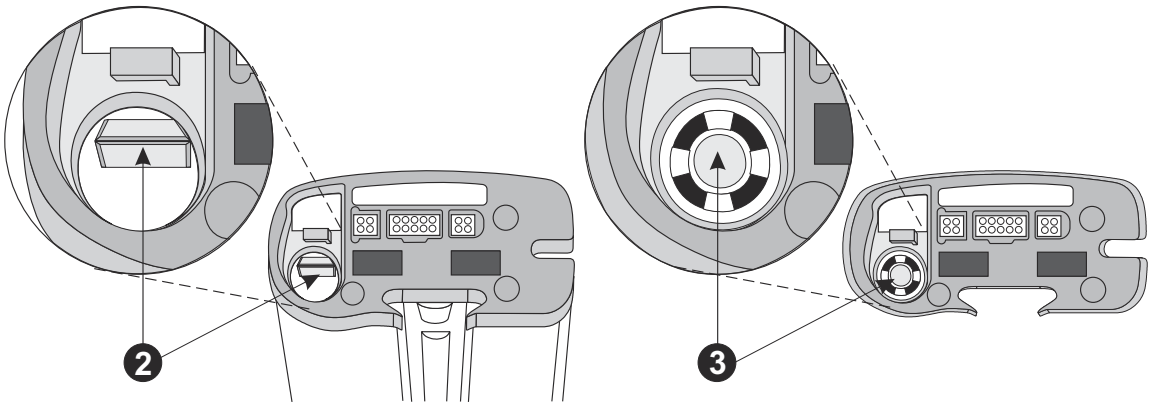
Figure 5-10. Battery Door Inspection

5.1.2.9.3

Battery Compartment Inspection

See *Figure 5-11, Battery Compartment Inspection*, and complete the following steps:

1. Remove the battery door.
2. Verify the circuit board wiper contact is present and free of contamination, corrosion, and excessive deformation.
3. Verify the battery cap is present and free of contamination and corrosion.



02G02029

Figure 5-11. Battery Compartment Inspection

5.1.2.10

POWER-ON TEST

See *Figure 5-12, Power-On Test,* and complete the following steps:

1. Install two fresh, disposable AA batteries in the infuser.
2. Press [ON/OFF]. Verify the infuser powers on and UNIT SELF-TEST displays, along with the time and date.
3. Verify the audible alarm sounds at power-on.
4. Verify USING BATTERIES displays, and press [YES/ENTER].
5. Connect the AC adaptor to the 3 volt connector on the bottom of the infuser, and verify the green power LED illuminates.
6. Disconnect the AC adaptor, and verify the green power LED is not illuminated.
7. Remove the battery door. Verify the red LED illuminates, the beeper sounds, and POWER LOSS displays.

Figure 5-12. Power-On Test

5.1.2.11

RECHARGEABLE BATTERY PACK (OPTIONAL)

See *Figure 5-13, Rechargeable Battery Pack*, and complete the following steps:

1. Verify the 3 V_{DC}/printer/bolus port connector contacts are present and in good condition.
2. Verify the 3 V_{DC}/printer/bolus pass-through port connector contacts are present and in good condition.

   CAUTION: Do not touch exposed connectors on the bottom of the infuser. Exposed connectors are susceptible to electrostatic discharge (ESD) damage.

3. Connect the infuser, without batteries, to the battery pack, and verify the battery pack slides into place and locks firmly.
4. Press [ON/OFF], and verify the infuser powers on and the green LED on the infuser flashes slowly.
5. Press the release buttons, and verify the latch mechanism releases.
6. Connect the battery pack to the battery pack charger, and verify the battery pack LED illuminates.

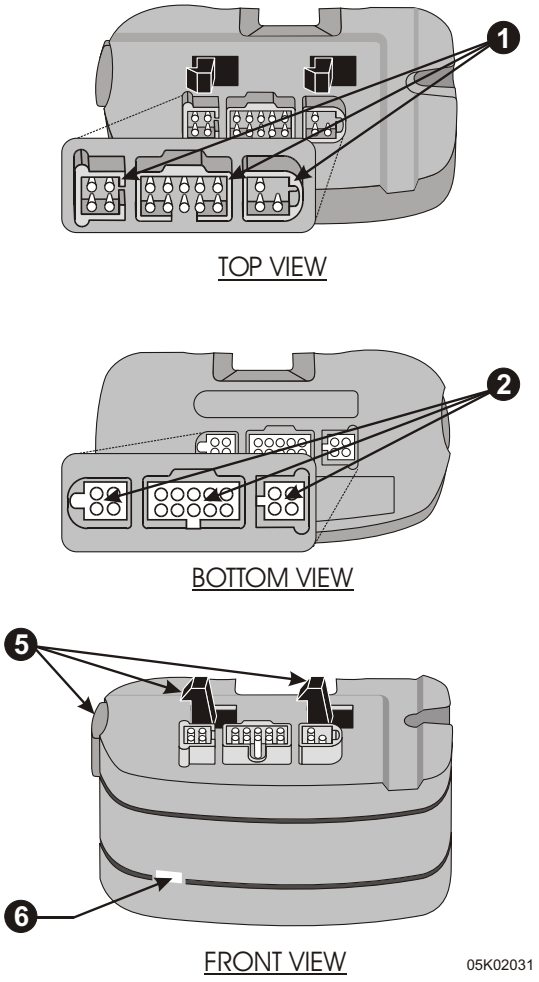


Figure 5-13. Rechargeable Battery Pack

5.1.2.12

DOCKING STATION (OPTIONAL)

See *Figure 5-14, Docking Station,* and complete the following steps:

1. Verify the dovetail is in good condition.
2. Press the release button, and verify the detent retracts.
3. Verify the 3 V_{DC}/printer/bolus port connector contacts are present and in good condition.

   CAUTION: Do not touch exposed connectors on the bottom of the infuser. Exposed connectors are susceptible to electrostatic discharge (ESD) damage.

4. Remove the connector cap and verify the bolus and printer pass-through port connector contacts are present and in good condition.
5. Verify the pole clamp is securely attached to the docking station body.
6. Verify the docking station is free of contamination, cracks, and other physical damage.
7. Verify the AC mains power cord lanyard and retention features are present.
8. Verify the AC mains power cord, plug, and prongs are in good condition.
9. Connect the docking station to AC mains power, and verify the docking station LED illuminates.
10. Slide the infuser, without batteries, into the docking station, and verify the device locks firmly into place.
11. Press [ON/OFF], and verify the infuser powers on and initiates the self test.
12. Remove the infuser, disconnect power, and perform a continuity test between the corresponding top and bottom pins to verify bolus pass-through functionality.

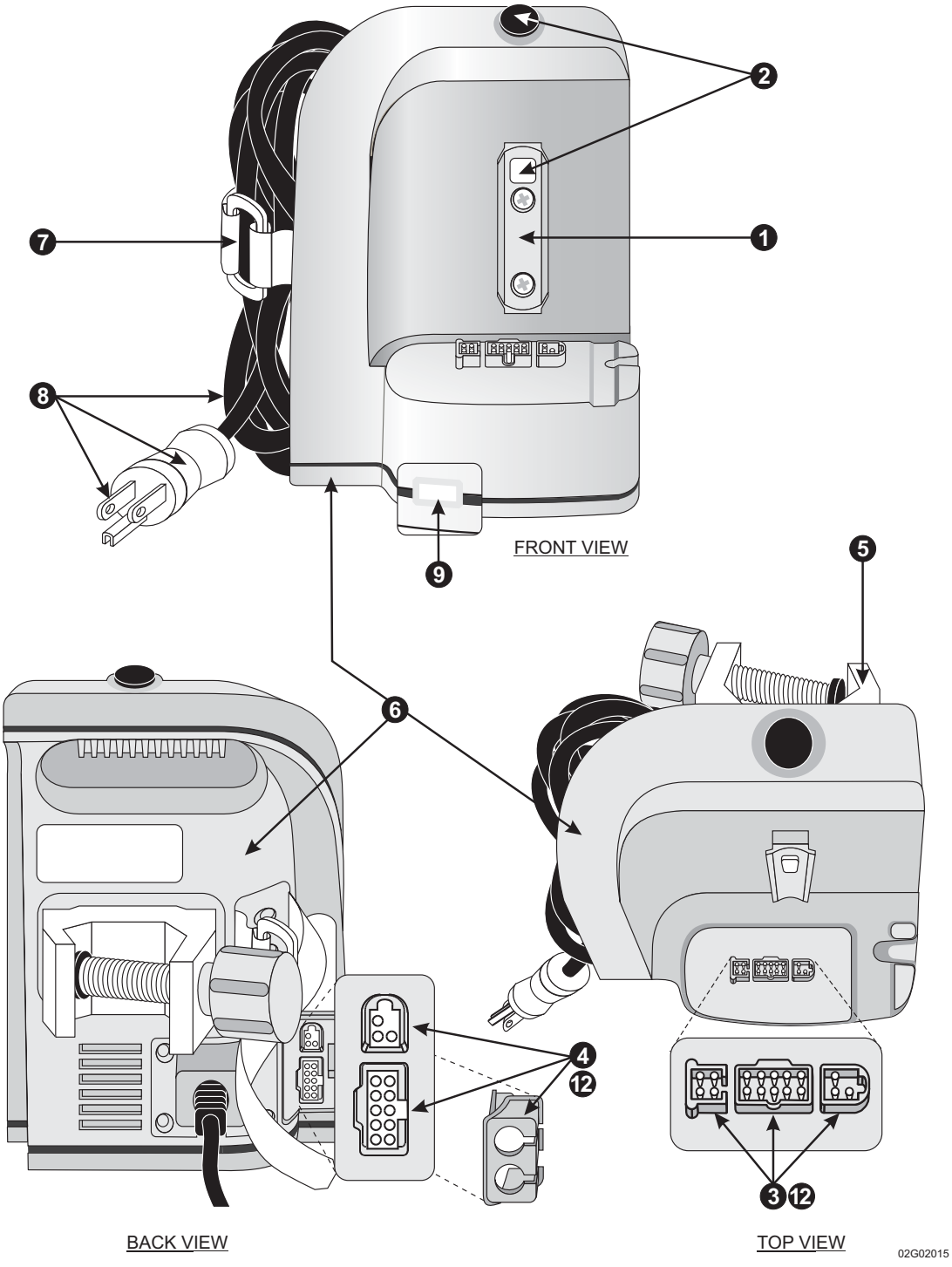


Figure 5-14. Docking Station

5.1.2.13

AC ADAPTOR (OPTIONAL)

CAUTION: Do not use the AC adaptor if the cord is frayed or torn insulation is found, or if any prong is missing from the plug.

See *Figure 5-15, AC Adaptor,* and complete the following steps:

1. Using a multimeter and probes, verify the AC adaptor output is 3 V_{DC} ± 5 %.
2. Verify the cord is in good condition.
3. Verify the transformer and 3-prong plug are in good condition.
4. Verify the infuser plug adaptor pins are present and in good condition.
5. Connect the AC adaptor to the adaptor port on the bottom of the infuser. Verify the AC plug is properly engaged/retained.
6. Remove the batteries.
7. Press [ON/OFF], and verify the infuser powers on.

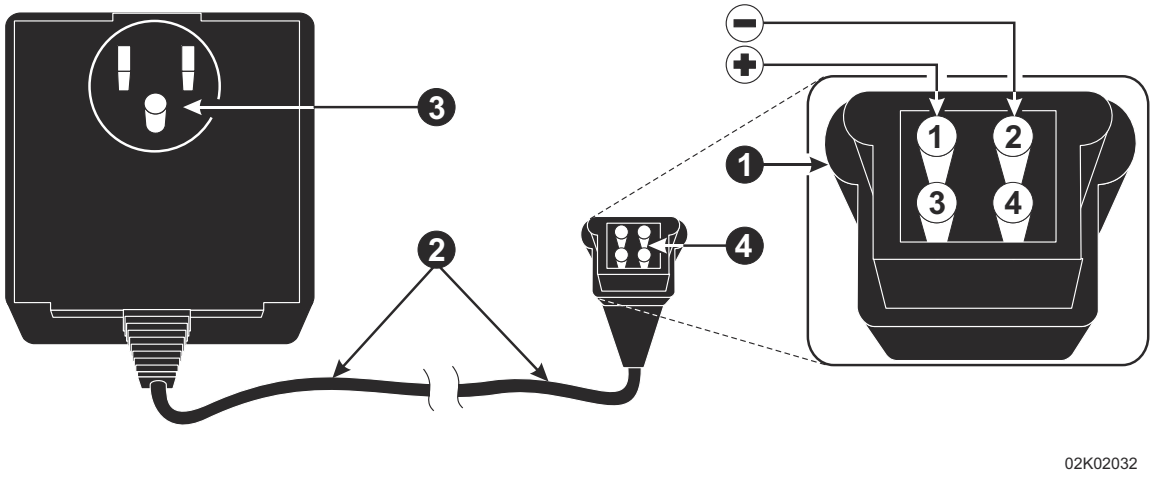


Figure 5-15. AC Adaptor

5.1.2.14

REMOTE BOLUS CORD AND SWITCH (OPTIONAL)

See *Figure 5-16, Remote Bolus Cord and Switch,* and complete the following steps:

1. Verify the bolus cord is free from fraying and torn insulation.
2. Verify the switch body is free of damage and evidence of fluid ingress.
3. Verify the bolus port connector pins are present and in good condition.
4. Press the bolus switch, and verify the bolus continuity across pins 1 and 2.
5. Connect the bolus cord to the bolus port on the bottom of the infuser. Verify the bolus cord plug is properly engaged/retained.

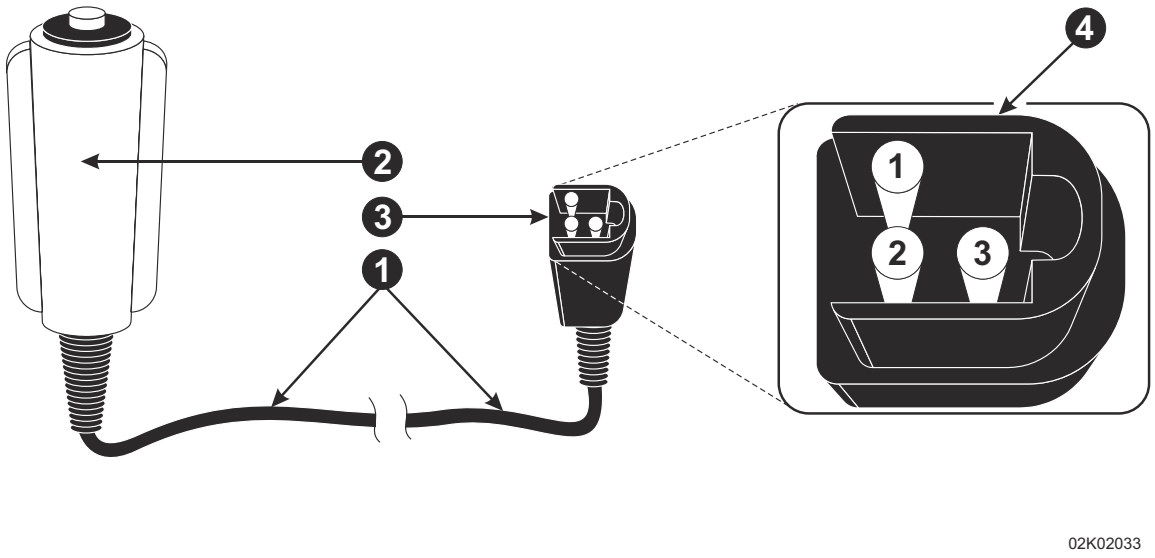


Figure 5-16. Remote Bolus Cord and Switch

5.2
PERFORMANCE VERIFICATION TEST

The performance verification test is designed to assure that the infuser is operating properly. Hospira recommends performing the performance verification test a minimum of once every 12 months. Refer to facility requirements to determine additional testing needs.

The test can be performed when the infuser is in the STOP mode and requires approximately 15 minutes to complete. Each section of the test must be run in sequence. The infuser automatically sets the delivery rate when required during the onboard operation test.

The infuser has an onboard feature called the operation test. It is accessed through the Histories menu, and provides step-by-step guidance through the onboard section of the performance verification test. Follow the instructions on the display to complete the onboard tests and then follow the instructions in this manual to perform the remaining tests; that is, the advanced distal and proximal occlusion tests.

Note: The infuser clears any program and shift totals stored in memory before starting the operation test.

Use the GemStar Performance Verification Test Checklist (*see Section 5.2.2*) to record test results.

Note: This test is available only when the infuser is UNLOCKED.

WARNING:	**A PATIENT SHOULD NEVER BE CONNECTED TO THE INFUSER DURING TESTING.**

5.2.1
EQUIPMENT REQUIRED

The performance verification test requires the following equipment, or equivalents:

- Primary Microbore GemStar Set, Attached PAV, Yellow Striped Tubing (List 13751)
- Primary GemStar Set, Piggyback with Backcheck Valve, 2 Clave™ Y-Sites (List 14265)
- I.V. bag with fluid
- Graduated cylinder, 25 mL, graduated in 0.2 mL, Class A
- Collection vessel
- Digital Pressure Meter (DPM) with max peak hold detection function (Fluke™ 717 or equivalent)
- Hemostat clamp
- Two fresh, disposable AA batteries
- Hospira-approved AC adaptor
- Serial printer cable, List Number 13078

5.2.2
PERFORMANCE VERIFICATION TEST CHECKLIST

The checklist below may be copied to record test results

1. Mark PASS or FAIL in the respective box after each test is performed.
2. For the Advanced Distal Occlusion Test, record the pressure readings in the spaces provided and mark PASS or FAIL.
3. For the Advanced Proximal Occlusion Test, verify the psi reading and mark PASS or FAIL.
4. Enter the device model and serial number in the space provided.
5. Sign and date this form in the space provided.

GemStar Performance Verification Test Checklist		
	Pass	**Fail**
Power Test	❑	❑
Keypad Test	❑	❑
Display Test	❑	❑
LED Test	❑	❑
Volume Accuracy Test	❑	❑
Distal Occlusion Test	❑	❑
Proximal Occlusion Test	❑	❑
Air-in-Line Test	❑	❑
Advanced Distal Occlusion Test Level — Acceptable Range — Actual Reading Low — 2 to 12 psi — _____ Medium — 4 to 20 psi — _____ High — 12 to 40 psi — _____	❑	❑
Advanced Proximal Occlusion Test	❑ Less than or equal to -4.0 psi	❑ Greater than -4.0 psi
Serial Number:		
Verified By:	Date:	

5.2.3
PRIMING AN ADMINISTRATION SET

The instructions below describe how to manually prime an administration set for the performance verification test.

Prime a microbore administration set (List 13751) for the volume accuracy test.

Prime an administration set with two Clave Y-sites (List 14265) for the advanced distal and proximal occlusion tests.

1. Push down on the flow stop to close the cassette (*see Figure 5-17*).

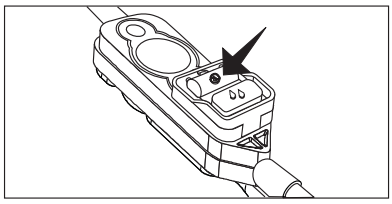


Figure 5-17. Close Flow Stop

2. Insert the piercing pin into the I.V. bag and hang on the I.V. pole.
3. Squeeze the drip chamber until filled halfway.
4. Push down on the flow stop (*see Figure 5-18*) to open the cassette and open all clamps.

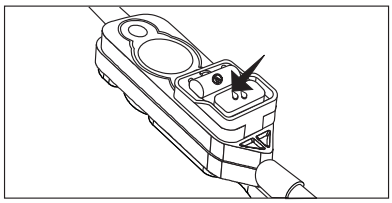


Figure 5-18. Open Flow Stop

5. Squeeze the I.V. bag to move fluid into the administration set and continue priming until fluid fills the tubing.
6. Starting at the proximal end of the administration set, invert and tap the backcheck valve, Y-sites, and cassette to expel residual air.
7. Confirm that the set is fully primed and all air bubbles have been removed.
8. Push down on the flow stop to close the cassette.
9. Confirm that the lower clamp is open and load the cassette.

Note: Air trapped in the administration set may cause volume accuracy test failure due to under delivery. Verify that air has been completely removed from the administration set cassette and tubing before starting the performance verification test.

5.2.4
TEST SETUP

1. Connect the external power source and install two fresh, disposable AA batteries.
2. Power on the infuser, and press [OPTIONS].
3. Select HISTORIES from the Options menu.
4. Select OPERATION TEST from the Histories menu, and follow the instructions on the display.

Note: The infuser clears any program and shift totals stored in memory before starting the onboard operation test.

5.2.5
POWER TEST

1. The display indicates an external power source and batteries are connected (*see Figure 5-12*).
2. Remove the disposable AA batteries and press [▼]. The display indicates that only external power is connected. Press [▼].
3. Install the batteries.
4. Disconnect the external power source and press [▼].
5. The display indicates that only batteries are connected and displays the test results. Press [▼].
6. If the test fails, reconnect the external power source and press [▲] to rerun the test, or press [YES/ENTER] to confirm failure.

5.2.6
KEYPAD TEST

1. Press each key, including the bolus button. Press [YES/ENTER] last.
2. Enter one of the following results:
   - If each key makes an audible tone, press [YES/ENTER].
   - If any key does not make an audible tone, press [NO].

5.2.7
DISPLAY TEST

1. Press [YES/ENTER] when prompted. The display fills with solid boxes for approximately ten seconds. To view the solid boxes for another ten seconds after the display times out, press [▲].
2. Enter one of the following results:
   - If the display fills with solid boxes, press [YES/ENTER].
   - If the display does not fill with solid boxes, press [NO].

5.2.8
LED TEST

1. Verify the green power LED and red alarm LED illuminate (*see Figure 5-12*).
2. Enter one of the following results:
   - If both LEDs illuminate, press [YES/ENTER].
   - If either of the LEDs does not illuminate, press [NO].

5.2.9
VOLUME ACCURACY TEST

To pass the volume accuracy test, the infuser must deliver between 19 and 21 mL within approximately three minutes.

5.2.9.1
EQUIPMENT REQUIRED

The volume accuracy test requires the following equipment or equivalents:

- Primary Microbore GemStar Set, Attached PAV, Yellow Striped Tubing (List 13751)
- I.V. bag with fluid
- 25 mL graduated cylinder (graduated in 0.2 mL, Class A)

5.2.9.2
TEST SETUP

1. Using a microbore administration set (List 13751), pierce the I.V. bag with the piercing pin and hang on an I.V. pole.
2. Prime the administration set (*see Section 5.2.3*).
3. Set up the equipment as shown in *Figure 5-19, Volume Accuracy Test Setup*.

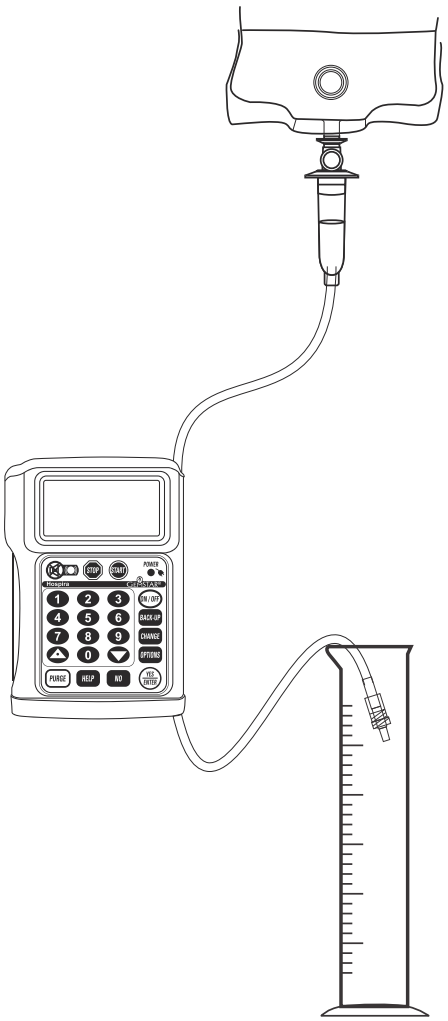


Figure 5-19. Volume Accuracy Test Setup

5.2.9.3

VOLUME ACCURACY TEST

1. Load the primed administration set (*see Section 5.2.3*) into the infuser and press the [▼] arrow.
2. Press the [▼] arrow again.
3. Verify that the 25 mL cylinder is emptied and dry.
4. Place the distal end of the administration set in the cylinder (*see Figure 5-19, Volume Accuracy Test Setup*) and press the [▼] arrow.
5. Press [START]. The infuser will deliver approximately 20 mL.
6. When the delivery is complete, read the fluid level at the bottom of the fluid meniscus (*see Figure 5-20*).

Note: It is necessary to read the fluid level at the bottom of the meniscus for an accurate reading.

Figure 5-20. Reading the Meniscus

7. If the infuser delivers between 19 and 21 mL, the infuser passed the test. Press [YES/ENTER] and continue on to the remaining onboard tests. If the infuser does not deliver between 19 and 21 mL, it failed the test. Press [NO] and follow the instructions in *Section 5.2.9.3.1*.

5.2.9.3.1

Retesting the Volume Accuracy

When the infuser fails the volume accuracy test:

1. Continue on to the remaining onboard tests.
2. Remove the administration set and prime it again, making sure to tap on the back check valve, Y-sites, and cassette to remove residual air (*see Section 5.2.3*). Using a new, primed administration set is also recommended.
3. Rerun the volume accuracy test. In order to do this, you must rerun the entire operation test (*Section 5.2*).

Note: Causes for volume accuracy test failure include:

- Air in cassette
- Air bubble delivered during testing
- Leak in fluid pathway
- Over-use of administration set

5.2.10
DISTAL OCCLUSION TEST

To pass the distal occlusion test, the occlusion must occur within approximately 30 seconds.

1. Clamp the administration set 10 to 12 inches (25.4 to 30.5 cm) below the cassette.
2. Press [START].
3. One of the following test results displays. Release the clamp and press [▼].
   - If the test has passed, the infuser advances to the next test.
   - If the test has failed, clean the sensors and press [▲] to rerun the test, or press [YES/ENTER] to confirm failure.

5.2.11
PROXIMAL OCCLUSION TEST

To pass the proximal occlusion test, the occlusion must occur within approximately 30 seconds.

1. Clamp the administration set above the cassette.
2. Press [START].
3. One of the following test results displays. Release the clamp and press [▼].
   - If the test has passed, the infuser advances to the next test.
   - If the test has failed, clean the sensors and press [▲] to rerun the test, or press [YES/ENTER] to confirm failure.

✎ **Note:** Clean the sensor pins before repeating the proximal occlusion test (*see Section 5.1.1.2*).

5.2.12
AIR-IN-LINE TEST

To pass the air-in-line test, the alarm must occur within approximately one minute.

1. Release the clamp.
2. Remove the proximal end of the set from the I.V. bag, and press [▼].
3. Press [START].
4. One of the following test results displays. Press [▼].
   - If the test has passed, the infuser advances to the next test.
   - If the test has failed, clean the sensors and press [▲] to rerun the test, or press [YES/ENTER] to confirm the failure.

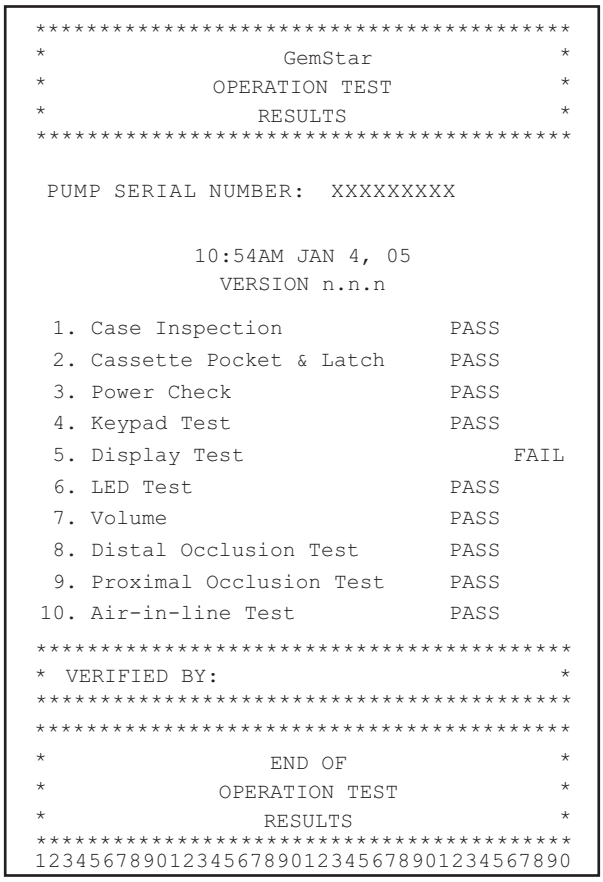
5.2.13
PRINTING THE TEST RESULTS

When the onboard test is complete, the infuser displays an option to print the test results. Follow Steps 1 through 3 to print the test results (*see Figure 5-21, Sample Test Result Printout*).

Note: For maximum battery life, the infuser should be operated on AC mains power when connected to a printer or computer.

1. Connect the serial printer cable (List 13078) to the infuser. Refer to the system operating manual for more information.
2. Press [YES/ENTER] to print the test results.
3. After the results have been transmitted to the printer, or if [NO] is pressed, the infuser automatically proceeds to the main programming menu.

Note: If the infuser failed the volume accuracy test, go to *Step 2 in Section 5.2.9.3.1*.



04K0203

Figure 5-21. Sample Test Result Printout

5.2.14
ADVANCED DISTAL AND PROXIMAL OCCLUSION TESTS

The following section describes the equipment setup, infuser programming, and instructions for advanced distal and proximal occlusion tests. These manual tests are not contained in the onboard operation test; however, they are part of performance verification test.

Hospira recommends performing these tests a minimum of once every 12 months.

5.2.14.1
EQUIPMENT REQUIRED

The advanced distal and proximal occlusion tests require the following equipment, or equivalents:

- Primary GemStar Set, Piggyback with Backcheck Valve, 2 Clave Y-Sites (List 14265)
- I.V. bag with fluid
- Collection vessel
- Digital Pressure Meter (DPM) with max peak hold detection function (Fluke 717 or equivalent)
- Hemostat clamp
- Hospira GemStar

5.2.14.2
BASIC TEST SETUP

1. Remove the microbore administration set used for the volume accuracy test from the infuser and from the I.V. bag.
2. Using an administration set with two Clave Y-sites (List 14265), pierce the I.V. bag with the piercing pin and hang the I.V. bag on an I.V. pole.
3. Prime the administration set (*see Section 5.2.3*).
4. Load the primed administration set into the infuser.
5. Place the distal end of the administration set tubing in to the collection vessel.
6. Place the DPM next to the collection vessel with the DPM display screen facing you.

5.2.14.3
BASIC PROGRAMMING

The following are the basic programming steps for the occlusion tests. The prompts that appear may vary depending on the model of infuser being programmed.

1. Power on the infuser, and wait for self test to complete.

   If a program already exists, select [2] CLR PROG&SHIFT.
2. If the delivery mode prompt appears, set the delivery mode to CONTINUOUS.
3. Set the unit of measure to mL.
4. Set the rate to 25.0 mL/hr at the SET RATE screen.

5. If the PROGRAM A LOADING DOSE? prompt appears, select NO.
6. If the SET VTBI screen appears, set the VTBI to 10.
7. If the SET KVO RATE screen appears, set the KVO Rate to 1 mL.
8. If the CONTAINER SIZE screen appears, set the Container Size to 20.0.
9. If the AIR SENSITIVITY screen appears, set the air sensitivity to ON.

5.2.14.4

ADVANCED DISTAL OCCLUSION TEST

This tests the infuser's ability to detect an occlusion in the section of tubing that goes from the infuser to the patient.

1. Connect the administration set's distal Clave port to the DPM (*see Figure 5-22*).
2. Turn on the DPM and zero (tare) the meter's pressure display.
3. Place the distal end of the tubing in to the collection vessel.
4. On the GemStar press [OPTIONS] and then press [4] to select PUMP SETTINGS.
5. Press [2] to select OCCL SENSOR.
6. Set the default pressure to LOW.
7. If the MAKE DEFAULT? prompt appears, press [YES/ENTER].
8. Review the program.

   If the program is accurate, press [YES/ENTER].

   If the program is inaccurate, press [BACK UP] and correct the program.
9. Press [START] and verify that fluid is flowing in to the collection vessel.
10. Using the hemostat, clamp the tubing between the distal Y-site and the distal end (*see Figure 5-22*).

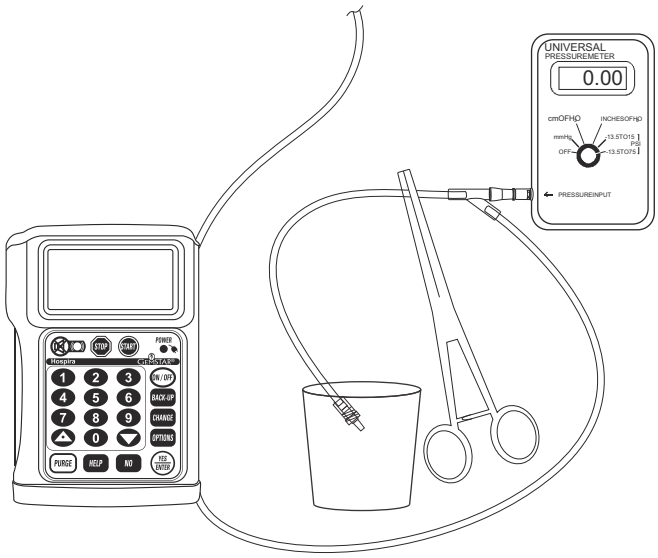


Figure 5-22. Testing for Distal Occlusion

11. When the occlusion alarm on the infuser sounds, check the pressure reading displayed on the DPM and record it on the GemStar Performance Verification Test Checklist (*see Section 5.2.2*).
12. Press [STOP] and remove the clamp from the tubing to release pressure.
13. Repeat Steps 4 to 12, setting the default pressure to MEDIUM in Step 6.
14. Repeat Steps 4 to 12, setting the default pressure to HIGH in Step 6.
15. Compare the LOW, MEDIUM, and HIGH pressure readings to the acceptable ranges shown in *Table 5-2, Distal Pressure Level Ranges*.

Table 5-2. Distal Pressure Level Ranges

Pressure Level Settings	Acceptable Range
LOW	2 to 12 psi
MEDIUM	4 to 20 psi
HIGH	12 to 40 psi

Note: If the distal pressure readings are outside of the acceptable range for any setting *Contact Hospira*.

16. Remove the distal Clave port from the DPM.

5.2.14.5

ADVANCED PROXIMAL OCCLUSION TEST

This tests the infuser's ability to detect an occlusion in the section of tubing that goes from the I. V. bag to the infuser.

1. Connect the administration set's proximal Clave port to the DPM and place the distal end of the tubing in the collection vessel (*see Figure 5-23*).
2. Turn on the DPM and zero (tare) the meter's pressure display.
3. On the GemStar infuser press [START].
4. Verify that fluid is being pumped out of the distal end into the collection vessel.
5. Using the hemostat, clamp off the tubing between the proximal Y-site and the backcheck valve (*see Figure 5-23*).

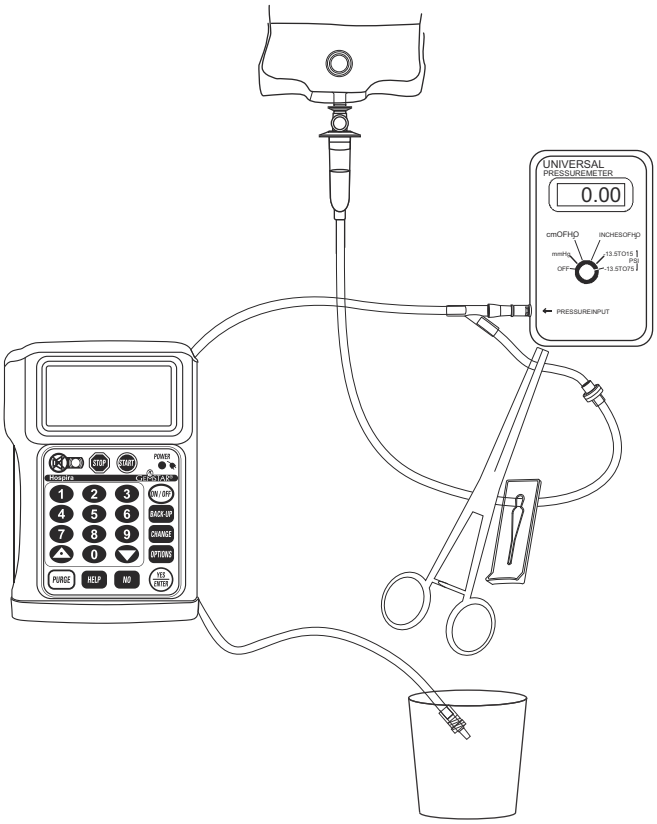


Figure 5-23. Testing for Proximal Occlusion

6. After the occlusion alarm sounds, check the pressure reading and record it on the GemStar Performance Verification Test Checklist (*see Section 5.2.2*).
7. Press [STOP].
8. Compare the pressure reading to the limits shown in *Table 5-3*.

Table 5-3. Proximal Pressure Readings

IF	THEN
The reading is less than or equal to -4.0 psi	The infuser passed the proximal occlusion test.
The reading is greater than -4.0 psi	The infuser failed the proximal occlusion test. *Contact Hospira*.

Note: If the proximal pressure levels are outside of the acceptable ranges *Contact Hospira*.

5.2.15
RESTORING THE INFUSER FOR USE

Before returning the infuser for use, it must be initialized. Initializing the infuser automatically performs the following functions:

- Resets the configuration registers
- Performs a power-on test
- Clears the error log
- Resets RAM variables
- Sets the default beeper level
- Clears user history

To initialize the infuser for use, complete the following steps:

1. Power on the infuser with a 3.0 V_{DC} AC adaptor only (no internal batteries).
2. At the power status display, press and hold [OPTIONS] until ENTER ACCESS CODE displays. Ignore the stuck key alarm that will sound while [OPTIONS] is pressed.
3. Enter access code **72255**. Asterisks display as the numbers are entered.

Note: Press [CHANGE} to clear an entry and enter a new code. An invalid code causes the infuser to return to the power-on self test.

4. Press [0][2] to select INT PUMP.
5. Turn off the infuser when initialization is complete.

5.3
PERIODIC MAINTENANCE INSPECTION

Periodic maintenance inspections should be performed per hospital procedures for compliance to accreditation requirements. It is recommended that JCAHO and/or hospital protocol be followed for establishing a periodic maintenance inspection schedule. Product specifications for this inspection are listed in *Section 8, Specifications*.

To perform the periodic maintenance inspection, complete the performance verification test in *Section 5.2*.

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Section 6

TROUBLESHOOTING

This section contains information on technical assistance, troubleshooting references, service alarms, and operational alarms for the GemStar infuser.

6.1
TECHNICAL ASSISTANCE

For technical assistance and product return authorization, and to order parts, accessories, or manuals within the United States, contact Hospira Technical Support Operations.

1-800-241-4002

For additional technical assistance, technical training, and product information, visit the website at www.hospira.com**.**

For technical assistance, product return authorization, and to order parts, accessories, or manuals from outside the United States, contact the nearest Hospira sales office.

6.2
TROUBLESHOOTING REFERENCES

The following information is provided to assist in troubleshooting the GemStar.

Under most alarm conditions, the infuser ceases normal operation, generates an audible alarm, and displays an alarm message or error code on the LCD screen.

Troubleshooting should always start with a basic infuser inspection to isolate and eliminate common infuser/cassette interface problems and user errors. Most problems can be easily resolved through non-invasive recovery procedures.

6.2.1
TROUBLESHOOTING TOOLS

Table 6-1, Troubleshooting Tools, describes the tools available to help isolate and resolve many infuser problems.

Table 6-1. Troubleshooting Tools

Section	Description	Purpose
6.2.2	Alert/alarm message index	Provides the appropriate reference for a specific error type
6.2.3	Printing device history	Provides significant events, in chronological order, such as programming and infuser performance history
5.1.2	Inspection	Provides information for inspecting the physical and functional parameters of the infuser to assure optimal performance
5.2	Performance verification test	Verifies infuser operation, including programmability, pressure and air sensitivity, and volume accuracy

6.2.2
ALERT/ALARM MESSAGE INDEX

Table 6-2, Alert/Alarm Message Index, describes error types, display messages, descriptions, and references.

Table 6-2. Alert/Alarm Message Index

Error Type	Display/Description	Reference
Alert message	ALMOST EMPTY CHECK PRINTER EMPTY CONTAINER FLASHING DISPLAY PROGRAM INCOMPLETE START	System operating manual
Sensor alarm	AIR-IN-LINE DISTAL OCCLUSION PROXIMAL OCCLUSION	
Alarm message	CHANGE BATTERIES CHECK CASSETTE LOW BATTERIES POWER LOSS USING BATTERIES	

Table 6-2. Alert/Alarm Message Index		
Error Type	**Display/Description**	**Reference**
Service alarm	CALL **1-800-241-4002** CODE: NN/MMM/TTT	*Section 6.1, Technical Assistance* *Section 6.3, Service Alarm Codes*
Other display messages	KEYPAD LOCKED	System operating manual
	NOT ALLOWED DURING INFUSION PROCESS PRESS STOP TO HALT DELIVERY	
	ROUNDING	
	DOSE IN PROGRESS NEW CONTAINER NOT ALLOWED	
	CANNOT CHANGE CLOCK WHILE THE BASE DELIVERY IS IN PROGRESS	
	PROGRAM EXCEEDS MAX CONTAINER SIZE CHANGE PROGRAM VALUES	
	THIS OPTION IS NOT AVAILABLE WHILE PROGRAMMING THE PUMP	
No display	No power or sign of functionality	*Section 6.1*
Locked up	Infuser is powered on but is not responding	*Section 5.2.15*

6.2.3
PRINTING DEVICE HISTORY

1. Power on the infuser.
2. Wait for the self test to complete, then press [YES/ENTER].
3. Connect the printer to the infuser.
4. Press [OPTIONS].
5. Select HISTORIES from the Options Menu.
6. Select HISTORY from the Histories menu to begin printing.

Note: Refer to the system operating manual for additional printing instructions and configuration settings.

6.3
SERVICE ALARM CODES

Service alarms indicate maintenance or repair of the infuser is required to restore proper infuser performance. Service alarm codes are displayed in the following format:

Primary	Supplemental	Type
NN	**MMM**	**TTT**

The following sections provide an explanation of service alarm codes, quick references, and service alarm code details.

6.3.1
SERVICE ALARM CODES - QUICK REFERENCE

Table 6-3, Service Alarm Codes - Quick Reference, lists error codes and descriptions.

Table 6-3. Service Alarm Codes - Quick Reference

Error	Description
01/000	CONFIG register contents are not what is expected
02/000	Stack error
03/000	Invalid interrupt
03/001	Interrupt overlap
03/002	Invalid IRQ interrupt
04/000	RAM Test error
05/000	EEPROM write error – data read back does not match data written
05/001	EEPROM write error – invalid EEPROM address
06/000	Pump configuration CRC error

Table 6-3. Service Alarm Codes - Quick Reference	
Error	**Description**
06/001	Infusion data CRC error
06/002	Pump data CRC error
06/003	Program data CRC error
06/004	Speed protocol CRC error
06/005	ROM CRC error
06/006	Protected variable error
06/007	Dose data CRC error
06/008	Air calibration CRC error
06/009	Pressure calibration CRC error
06/010	Motor calibration CRC error
06/011	Settings CRC error
07/000	High air sensor value
07/001	Negative volume sampled
07/002	Bad air sensor state
07/003	Bad air sensor event
07/004	Air sensor not calibrated
07/005	Excessive volume sampled
08/005	Bad pressure sensor event
08/006	Bad pressure sensor state
08/007	Distal pressure is out of range
08/008	Proximal pressure is out of range
09/000	Short term overdelivery
09/001	Backward motor movement
09/002	Motor not calibrated
09/006	Power on motor test
09/007	Motor not turning when it should be turning
09/008	Bad motor state
09/009	Bad motor event
09/010	Bad motor rate
09/011	Motor stack error
09/012	Motor step overlap
09/013	Motor control error

Table 6-3. Service Alarm Codes - Quick Reference	
Error	**Description**
09/014	Bad motor step number
09/015	Motor overshot IPRF step
09/016	Motor encoder overflow
09/017	Bad restart command
09/018	Motor overdelivery
09/019	Motor underdelivery
09/020	Motor runaway
10/000	Beeper error
11/000	More than 5.5 volts measured on the 5 V line
11/001	Less than 4.5 volts measured on the 5 V line
11/002	More than 3.2 volts measured on the AA battery voltage input
11/003	More than 3.6 volts measured on the external voltage input
11/004	Less than 2.0 volts measured on the lithium battery input
12/000	Stuck key
13/000	IRQ test of oscillator – timing error
13/001	RTI test of one second interrupt – timing error
14/001	Watchdog timeout – motor was turning when it should not be turning
14/003	Watchdog error – task not responding
15/000	Power down error
16/001	Air-in-line was active when it should not be active
16/002	Key event timeout
16/003	Invalid alarm semaphore
16/004	Invalid alarm message
16/005	Invalid alarm type
16/006	Invalid alarm callback
16/007	Invalid sound type
16/008	IQUEUE full
16/009	Infusion safety task received an invalid message type
16/010	Infusion safety task received a null message type
16/011	Infusion safety task received an invalid pressure message
16/012	Infusion safety task did not receive the expected queue information
16/013	Infusion safety task received an invalid semaphore value

Table 6-3. Service Alarm Codes - Quick Reference	
Error	**Description**
16/014	Infusion safety task received an invalid air message
16/015	Infusion safety task received an invalid check cassette message
16/016	Infusion safety task received a resume without an initial start
16/017	Infusion safety task detects a rate mismatch
16/018	Infusion safety task detects a mode mismatch
16/019	IED has message conflict
16/020	Remote queue out full
16/021	Remote queue out empty
16/022	Remote queue out bad state
16/023	ISA bad rate
18/000	History pointer error while inserting a new record into the history log
18/001	History pointer error while traversing to bottom of history
18/002	History pointer error while traversing to top of history
21/000	Remote communication input buffer error
21/001	Keypad queue error
21/002	Remote communication input message error

6.3.2
SERVICE ALARM CODES - DETAILS

Table 6-4, Service Alarm Codes - Details, lists primary errors, supplemental errors, types, error detection methods, error descriptions, and possible causes.

Table 6-4. Service Alarm Codes - Details

Primary Error (NN)	Supplemental Error (MMM)	Type (TTT)	Error Detection Method	Error Description and Possible Cause
01 CPU_ERROR	**000** CONFIG_REG	CONFIG register contents	At power on, the contents of the CONFIG register is tested for the expected value. If the contents are invalid, a service alarm occurs.	The CONFIG register does not contain the expected value due to: CPU failure EEPROM failure
02 STACK_ ERROR	**000**	Stack # **0** = RTXC stack **1** = SCI_INPUT stack **2** = SCI_OUTPUT stack **3** = IED stack **4** = UI stack **5** = DISPMGR stack **6** = INFUSION stack **7** = ISAFETY stack **8** = ALARM stack **9** = NISAFETY stack **10** = HISTORY stack **11** = REMOTE OUT stack **12** = STACKMAX	Each stack is initialized during power on. Once per second, these values are checked for corruption. If a guard byte has been overwritten, a service alarm occurs.	Stack overflowed due to: CPU failure Flash RAM failure RAM chip failure Bus failure
03 INTERRUPT_ ERROR	**000** INVALID_ INTERRUPT	Interrupt # **1** = SPI_INTERRUPT **2** = PAIE_INTERRUPT **11** = TIC2_INTERRUPT **12** = TIC1_INTERRUPT **18** = NOCOP_ INTERRUPT **19** = CME_INTERRUPT	All unsupported ISRs, when called, are trapped in a service alarm	An unsupported interrupt has been called due to: Flash RAM failure Bus failure CPU failure RAM chip failure

Table 6-4. Service Alarm Codes - Details

Primary Error (NN)	Supplemental Error (MMM)	Type (TTT)	Error Detection Method	Error Description and Possible Cause
03 INTERRUPT_ ERROR	**001** INTERRUPT_ OVERLAP	Interrupt # **0** = SCI_INTERRUPT serial port **3** = PAO_INTERRUPT motor forward counts = 256 **4** = TO_INTERRUPT timer overflow; general purpose timing **5** = TOC5_INTERRUPT air monitoring **6** = TOC4_INTERRUPT keypad scanning **7** = TOC3_INTERRUPT pressure monitoring **8** = TOC2_INTERRUPT motor control **9** = TOC1_INTERRUPT output shaft sensor scanning **10** = TIC3_INTERRUPT motor backward ticks **13** = RTI_INTERRUPT system clock; watchdog servicing; stack checking) **14** = IRQ_INTERRUPT real-time clock chip interrupt **15** = XIRQ_INTERRUPT power loss	Each interrupt service routine has a unique activity flag associated with it. The flag is set upon entry into the ISR and cleared upon exit. If, on entry, the flag is already set, a service alarm occurs.	An interrupt was called again before the last execution completed due to: Flash RAM failure Bus failure CPU overload
	002 INVALID_IRQ_ INTERRUPT	IRQ status byte	Upon entry into the ISR, a processing flag is set to FAILURE. As the individual bits are processed, the flag is set to SUCCESS. If no flags are processed, a service alarm occurs.	The IRQ interrupt was called but no interrupts were processed due to: CPU failure FPGA failure timer chip failure output shaft sensor failure
04 RAM_ERROR	**000** INTERNAL_ TEST	Test # **0** = Power on test **1** = Background test	At power on and continuously during operation, all RAM locations are tested by writing patterns of 0XAA and 0X55 and by address count up.	Read/write test to internal RAM failed due to: CPU failure

Table 6-4. Service Alarm Codes - Details

Primary Error (NN)	Supplemental Error (MMM)	Type (TTT)	Error Detection Method	Error Description and Possible Cause
05 EEPROM_ WR_ERROR	**000**	N/A	All writes to CPU EEPROM are processed via a common function which reads back the EEPROM contents following a write. If the data read back following the write does not match the data written, a service alarm occurs.	Unable to write to EEPROM in the 68HC11 chip due to: CPU EEPROM failure CPU failure
	001	N/A	All writes to CPU EEPROM are processed via a common function. If the function receives an invalid EEPROM address, a service alarm occurs.	Unable to write to EEPROM in the 68HC11 chip due to: RAM chip failure Bus failure
06 CRC_ CHKSUM_ ERROR	**000** PUMP_ CONFIG_CRC	N/A	The configuration data integrity is verified: before viewing before printing before using in rate-lock change function before using in menu function at power on whenever any dose is started or restarted If the CRC stored with the configuration data does not match the calculated value, a service alarm occurs.	The computed configuration CRC value does not match the stored value due to: CPU EEPROM failure CRC calculation error

Table 6-4. Service Alarm Codes - Details

Primary Error (NN)	Supplemental Error (MMM)	Type (TTT)	Error Detection Method	Error Description and Possible Cause
06 CRC_ CHKSUM_ ERROR	**001** INFUSION_ DATA_CRC	N/A	The infusion data integrity is verified at power on and once per second while the infusion task is running. If an invalid infusion data pointer is found or if the CRC stored with the infusion data does not match the calculated value, a service alarm occurs.	The computed infusion data CRC does not match the stored value due to: RAM chip failure Bus failure CRC calculation error
	002 PUMP_DATA_ CRC	N/A	The infuser data integrity is verified at power on and once per second while the infusion task is running. If the CRC stored with the infuser data does not match the calculated value, a service alarm occurs.	The computed infuser data CRC does not match the stored value due to: RAM chip failure Bus failure CRC calculation error
	003 PROGRAM_ CRC	N/A	The infuser program data integrity is verified: entering stop mode entering run mode when a new program is sent to infusion whenever any dose starts or restarts If the CRC stored with the infuser program data does not match the calculated value, a service alarm occurs.	The computed infuser program CRC does not match the stored value due to: RAM chip failure Bus failure CRC calculation error

Table 6-4. Service Alarm Codes - Details

Primary Error (NN)	Supplemental Error (MMM)	Type (TTT)	Error Detection Method	Error Description and Possible Cause
06 CRC_ CHKSUM_ ERROR	**004** SPEED_ PROTOCOL_ CRC	Speed protocol #	The speed protocol data integrity is verified: before printing a speed protocol before viewing a speed protocol before assigning a speed protocol before deleting a speed protocol before retrieving a speed protocol If the CRC stored with the speed protocol data does not match the calculated value, a service alarm occurs.	The computed speed protocol CRC does not match the stored value due to: RAM chip failure CRC calculation error
	005 ROM_CRC	N/A	The Flash RAM data integrity is verified at power on and once every hour. If the checksum stored in the Flash RAM does not match the calculated value, a service alarm occurs.	The computed FLASH RAM checksum does not match the stored value
	006 PROTECTED_ VAR	Variable type **003** = Air state **004** = Pressure state **006** = Distal pressure threshold **007** = Proximal pressure threshold	Critical data used in air and pressure sensing is mirrored in RAM when written. When read back, the data and its mirrored value is compared to verify data integrity. If the data value cannot be verified, a service alarm occurs.	The protected variable value is corrupted due to: RAM chip failure Bus failure CPU failure

Table 6-4. Service Alarm Codes - Details

Primary Error (NN)	Supplemental Error (MMM)	Type (TTT)	Error Detection Method	Error Description and Possible Cause
06 CRC_ CHKSUM_ ERROR	**007** DOSE_DATA_ CRC	Dose type	The dose data integrity is verified at power on, once every second and at the start of a new dose. If the CRC stored with the dose data does not match the calculated value, a service alarm occurs.	The computed dose data CRC does not match the stored value due to: RAM chip failure CRC calculation error
	008 AIR_CAL_CRC	N/A	The air calibration data integrity is verified at power on and in the background. If the CRC stored with the air calibration data does not match the calculated value, a service alarm occurs.	The computed air calibration data CRC does not match the stored value due to: CPU EEPROM failure CRC calculation error
	009 PRESS_CAL_ CRC	N/A	The pressure calibration data integrity is verified at power on and in the background. If the CRC stored with the pressure calibration data does not match the calculated value, a service alarm occurs.	The computed pressure calibration data CRC does not match the stored value due to: CPU EEPROM failure CRC calculation error
	010 MOTOR_CAL_ CRC	N/A	The motor calibration data integrity is verified at power on and every time a start delivery command is sent to infusion safety. If the CRC stored with the motor calibration data does not match the calculated value, a service alarm occurs.	The computed motor calibration data CRC does not match the stored value due to: CPU EEPROM failure CRC calculation error

Table 6-4. Service Alarm Codes - Details

Primary Error (NN)	Supplemental Error (MMM)	Type (TTT)	Error Detection Method	Error Description and Possible Cause
06 CRC_ CHKSUM_ ERROR	**011** SETTINGS_ CRC	**0** = Error when entering a function that will alter the infuser settings **1** = Error when entering a function that displays the current lock levels	Verifies the settings data is correct when: displaying the lock levels entering Run mode or Stop mode changing the PM rate, PM bolus dose, or occlusion setting	One of the following is corrupted: lock level occlusion setting default occlusion setting PM rate lock ranges
07 AIR_ SENSOR_ ERROR	**000** HIGH_VALUE	Measured value	When evaluating the air sensor state, the measured pre-trigger value is compared with the level set during calibration. If the measured value is greater than the calibration value, a service alarm occurs.	Air sensor returning too high a value due to: calibration error air sensor receiver fault
	001 AIR_NEGATIVE _VOLUME	N/A	The volume delivered between checkpoints is calculated each checkpoint. If the volume is negative and more than one stroke has been delivered, a service alarm occurs.	Negative volume sampled due to: RAM chip failure 180 degree miscalibration of the output shaft encoder
	002 AIR_BAD_ STATE	State #	The state variable was not one of the recognized states for the pressure software.	The air sensor was in an invalid state due to: RAM chip failure
	003 AIR_BAD_ EVENT	Event #	If an event code is received that is not one of the recognized events for the air software, a service alarm occurs.	The air sensor received an invalid event due to: RAM chip failure
	004 AIR_NOT_ CALIBRATED	**0**	The AIR MAX PRE LEVEL is checked to see that it is not zero at power on If it is zero, a service alarm occurs.	The air sensor calibration values are not within the expected ranges due to: calibration error EEPROM failure

Table 6-4. Service Alarm Codes - Details

Primary Error (NN)	Supplemental Error (MMM)	Type (TTT)	Error Detection Method	Error Description and Possible Cause
07 AIR_ SENSOR_ ERROR	**005** AIR_ EXCESSIVE_ VOLUME	N/A	The volume delivered between checkpoints is calculated each checkpoint. If the volume exceeds 100 µL, a service alarm occurs.	Excessive volume sampled due to: RAM chip failure 180 degree miscalibration of the output shaft encoder CPU overload
08 PRESSURE_ SENSOR_ ERROR	**005** PRESS_BAD_ EVENT	Bad event #	Pressure sensor software checks events it receives against a list of valid events. If a received event is not in the list, a service alarm occurs.	The pressure sensor received an invalid event due to: RAM chip failure Bus failure
	006 PRESS_BAD_ STATE	State #	If processing is not defined for a state value, a service alarm occurs.	The pressure sensor state variable was invalid due to: RAM chip failure Bus failure
	007 PRESS_ DISTAL_ RANGE	N/A	When delivery is started and after the plunger passes home, the distal threshold is recomputed. If it is not in the 0–255 range, a service alarm occurs.	The distal pressure is out of range due to: corruption of calibration data used to compute pressure computation error in hardware or software RAM error
	008 PRESS_ PROX_ RANGE	N/A	When delivery is started, the proximal occlusion threshold is recomputed. If it is not in the 0–255 range, a service alarm occurs.	The proximal pressure is out of range due to: corruption of calibration data used to compute pressure computation error in hardware or software RAM error

Table 6-4. Service Alarm Codes - Details

Primary Error (NN)	Supplemental Error (MMM)	Type (TTT)	Error Detection Method	Error Description and Possible Cause
09 MOTOR_ ERROR	**000** MOTOR_IPRF_ ENC_OS_SYNC	Step where problem occurred	IPRF steps, in general, are expected to begin on the pump side of the stroke. If the microprocessor misses motor encoder counts, the plunger will advance further than it should, resulting in a short-term overdelivery. Before beginning to deliver the next step, the software tests the output shaft flag position to detect that it is still on the pump side of the stroke. There are several exceptions: Step 0 of any delivery Step 7 of an 8-step delivery Steps 13, 14, and 15 of a 16-step delivery	Microprocessor misses motor encoder counts This error will never be reported for single step IPRF (30.1 mL/hr to 125 mL/hr).

Table 6-4. Service Alarm Codes - Details

Primary Error (NN)	Supplemental Error (MMM)	Type (TTT)	Error Detection Method	Error Description and Possible Cause
09 MOTOR_ ERROR	**000** MOTOR_IPRF_ ENC_OS_SYNC	Step where problem occurred	The last step of a stroke frequently overshoots its stopping position, near full extension, so Step 0 often starts on the fill side. If the output shaft has the maximum positive offset (+10), all other steps can be expected to start on the output shaft flag. If the output shaft has the maximum negative offset (-30), any step beginning at a position under 186 should be expected to start on the output shaft flag. The steps that may not start on the flag is this case are: Step 7 of an 8-step delivery Steps 13, 14, and 15 of a 16-step delivery	Microprocessor misses motor encoder counts This error will never be reported for single step IPRF (30.1 mL/hr to 125 mL/hr).

Table 6-4. Service Alarm Codes - Details

Primary Error (NN)	Supplemental Error (MMM)	Type (TTT)	Error Detection Method	Error Description and Possible Cause
09 MOTOR_ ERROR	**001** MOTOR_ BACKWARD_ MOVEMENT	Type 1: single rollback greater than 40 counts number of backward encoder counts Type 2: excessive accumulation of rollbacks greater than 16 counts accumulated backward counts in excess of 16 Error log data, Type 1 only: **26/000/sss** **26/fff/bbb** **26/ppp/aaa** Where: **sss** = iprf step number **fff** = forward count register (*PACNT) **bbb** = total back ticks this stroke **ppp** = distal pressure (ADC) **aaa** = distal alarm flag (1 = alarm) For each rollback greater than 16 counts, error log contains: **29/ppp/rrr** **29/ccc/nnn** Where: **ppp** = distal pressure (ADC) **rrr** = rollback amount, ticks **ccc** = count of large rollbacks within this 16-stroke window **nnn** = net position (forward–back counts) at start of this step	Type 1: The motor encoder backward count accumulator tests the number of counts each time a count is accumulated. If the backward count exceeds the limit (40), a service alarm occurs. Type 2: Each time the motor is started, if the number of backward counts in the previous rollback is greater than 16, the amount in excess of 16 is accumulated. This accumulation is cleared every 16 strokes. If the accumulation exceeds 40 counts, a service alarm occurs.	Excessive motor backward movement due to: high distal pressure motor clutch failure motor gearbox failure

Table 6-4. Service Alarm Codes - Details

Primary Error (NN)	Supplemental Error (MMM)	Type (TTT)	Error Detection Method	Error Description and Possible Cause
09 MOTOR_ ERROR	**002** MOTOR_NOT_ CALIBRATED	Error type **0** = Invalid PWM **1** = Stroke volume **2** = Motor slope **4** = Output shaft offset	The motor calibration values are tested at power on to verify they are within expected ranges. If a value is out of range, a service alarm occurs. For each new rate, a PWM is calculated. If the calculated value is less than the minimum set during calibration, a service alarm occurs.	The motor calibration values are not within the expected ranges due to: calibration error EEPROM failure
	006 NO_MOTOR_ CONTROL	Error type **1** = Shorted switch FET **2** = Backward movement **3** = Motor does not turn **4** = Motor runs too fast **5** = Motor runs backward Error log data for **09/006/003**: **24/000/iii** **24/fff/ppp** Where: **iii** = motor current (ADC) **fff** = forward count register (*PACNT) **ppp** = distal pressure (ADC)	At power on, a motor test is performed to verify that, with other motor controls set, the motor does not turn when the motor switch FET is off and that the motor does turn when the motor switch FET is on. If a test fails, a service alarm occurs.	The power on motor control test failed independent motor switch FET failed motor wiring error motor encoder strobe failure motor encoder failure PIC became active (003) PIC failure (003)

Table 6-4. Service Alarm Codes - Details

Primary Error (NN)	Supplemental Error (MMM)	Type (TTT)	Error Detection Method	Error Description and Possible Cause
09 MOTOR_ ERROR	**007** MOTOR_NOT_ PUMPING	State #; Event # The type field is displayed as **xy**, where **x** is the state # and **y** is the event #. No movement while: **016** = Homing **036** = Stepping **046** = Continuous **066** = Ramping up Error log data: **25/fff/bbb** **25/vvv/iii** **25/sss/000** **25/ppp/aaa** **25/nnn/ttt** **25/ooo/eee** **25/ddd/ccc** **25/aal/prx** Where: **fff** = forward count register (*PACNT) **bbb** = mticks_ back_stroke **iii** = motor current (ADC) **vvv** = motor voltage (ADC) **sss** = motor speed (pwm) **ppp** = distal pressure (ADC) **aaa** = distal alarm local flag (1= alarm) **nnn** = motor encoder enable (1 = on) **ttt** = motor encoder strobe (1 = on) **ooo** = motor drive on (1 = on) **eee** = motor drive enable (1 = on) **ddd** = distal occlusion alarm condition (1 = on) **ccc** = check cassette alarm condition (1 = on) **aal** = air alarm condition (1 = on) **prx** = proximal occlusion alarm condition (1 = on)	Motor movement is tested during ramp up, IPRF homing, IPRF stepping, and continuous delivery. If the PWM value to the motor reaches 200 and no movement is detected, a service alarm occurs.	No encoder counts detected when the motor is supposed to be running due to: motor drive failure motor encoder strobe failure motor encoder failure PIC became active The motor was off when it should not be due to: independent motor switch FET fails off V+ regulator shorted to ground motor circuit open The motor has stalled, due to: motor drivetrain failure (high torque) high backpressure

Table 6-4. Service Alarm Codes - Details

Primary Error (NN)	Supplemental Error (MMM)	Type (TTT)	Error Detection Method	Error Description and Possible Cause
09 MOTOR_ ERROR	**008** MOTOR_BAD_ STATE	State #	If the motor state variable is out of range, a service alarm occurs.	The motor state variable was invalid due to: RAM chip failure
	009 MOTOR_BAD_ EVENT	State #; Event # The type field is displayed as **xy**, where **x** is the state # and **y** is the event #.	If event processing is not allowed within the current state, a service alarm occurs.	The motor received an invalid event due to: RAM chip failure
	010 MOTOR_BAD_ RATE	Error # **000** = IPRF rate: 0.1 mL/hr **001** = Continuous rate: 1000 mL/hr **002** = Taper time is zero **003** = Taper dose is zero **004** = Taper starting rate: 400 mL/hr **005** = Taper ending up rate: 400 mL/hr **006** = Taper down starting rate is zero **007** = Taper down dose cannot be delivered with the given starting rate and taper time	When a start command is received from the infusion task, the rate is verified to be within the acceptable range of values.	The motor received an invalid rate due to: RAM chip failure Bus failure
	011 MOTOR_ STACK_ ERROR	Error # **001** = Stack full **002** = Stack empty **003** = Invalid stack pointer detected when pushing onto the stack **004** = Invalid stack pointer detected when popping from the stack	The stack is checked for space available before a state is added to the stack and for no data present before a state is removed from the stack. If a stack request cannot be processed, a service alarm occurs.	An error was detected in processing the motor stack due to: RAM chip failure Bus failure
	012 MOTOR_ STEP_ OVERLAP	State #; Event # **15** = While homing **35** = While stepping	A timer is used to control IPRF motor steps. If the motor is homing or stepping when the timer expires, a service alarm occurs.	A motor step did not complete before the next step was requested due to: motor encoder strobe failure motor encoder failure motor encoder output failure motor clutch failure (high torque)

Table 6-4. Service Alarm Codes - Details

Primary Error (NN)	Supplemental Error (MMM)	Type (TTT)	Error Detection Method	Error Description and Possible Cause
09 MOTOR_ ERROR	**013** MOTOR_RATE_ CONTROL_ ERROR	Error # **001** = Initial calculation **002** = Normal operation **003** = Rate adjustment Error log data: **27/aaa/bbb** Where: **aaa** = counts steps (1 = on) **bbb** = step #	The PWM_LOW_ COUNTER value must always be between 0 and 10. When tested, if PWM_LOW_ COUNTER is ever greater than 10, the service alarm results.	Error due to: RAM chip failure Bus failure
	014 MOTOR_BAD_ STEP_NUM	Step #	At the end of each IPRF motor step, the step number is incremented and confirmed to be within the expected range for that delivery rate.	The motor was performing an invalid step due to: RAM chip failure Bus failure
	015 MOTOR_ OVERSHOT	Step # of the second (last) step that overshot Error log data: **23/000/sss** **23/mmm/nnn** **23/kkk/lll** **23/ggg/hhh** Where: **sss** = motor PWM **mmm/nnn** = NetBad2 = (mmm*100) + nnn NetBad2 reports the net counts (FINE_POS) as of the second consecutive overshot step reported in the **09/015** alarm **kkk/lll** = NetBad1 = (kkk * 100) + lll NetBad1 reports the net counts (FINE_POS) as of the step before the one reported in the **09/015** alarm **ggg/hhh** = NetGood = (ggg * 100) + hhh NetGood reports the net counts (FINE_POS) of the last step that was within tolerance (two steps before the one reported in the **09/015** alarm)	After each IPRF step, the software checks the actual stopping position. If two consecutive steps overshoot the stopping position by two points or more, a service alarm occurs.	The motor overshot the stopping position, due to: software control error motor encoder strobe failure motor encoder failure motor servo failure

Table 6-4. Service Alarm Codes - Details

Primary Error (NN)	Supplemental Error (MMM)	Type (TTT)	Error Detection Method	Error Description and Possible Cause
09 MOTOR_ ERROR	**016** MOTOR_ ENCODER_ OVERFLOW	Type 1: Pulse accumulator back counts in previous stroke Type 2: Output shaft scan pulse accumulator value Error log data, Type 1: **22/aaa/bbb** **22/ccc/ddd** **22/eee/fff** Where: **aaa** = IPRF step **bbb** = total turns (low byte) **ccc/ddd** = overflow ticks as 256 * ccc + ddd **eee/fff** = net counts forward minus backward as 256 * aaa + bbb Error log data, Type 2: **28/aaa/bbb** **28/ccc/ddd** **28/eee/fff** **28/ggg/hhh** **28/iii/jjj** Where: **aaa** = number of overflows **bbb** = whether pulse accumulator has overflowed since previous pulse accumulator interrupt **ccc/ddd** = forward limit, as 256 * ccc + ddd **eee/fff** = total forward counts, as 256 * eee + fff **ggg/hhh** = forward counts on previous turn **iii/jjj** = total turns since starting infuser	For purposes of this alarm, the maximum allowed number of forward motor counts per output shaft revolution is 432 + 80 + 8*N, where **N** is the number of times the motor stopped on the previous revolution. If the forward counts are found to exceed this value, a service alarm occurs.	The motor encoder overflow count was not cleared due to: output shaft sensor strobe failure output shaft sensor failure output shaft encoder levels out of spec., possibly due to sensor positioning; reflectivity of parts; component variations; supply voltage variations; open/short in OSE subsystem; flag mismounted stripped coupling gearbox failure other transmission failure

Table 6-4. Service Alarm Codes - Details

Primary Error (NN)	Supplemental Error (MMM)	Type (TTT)	Error Detection Method	Error Description and Possible Cause
09 MOTOR_ ERROR	**017** MOTOR_BAD_ RESTART	N/A	The motor ISR verifies that the current rate is not zero when it receives a restart command from the infusion task.	The motor received an invalid restart command due to: RAM chip failure Bus failure
	018 MOTOR_ OVER_ DELIVERY	Error **1** = Too fast **2** = Turns exceeded dose Error log data, if error = 1: **19/aaa/bbb** **19/ccc/ddd** Where: **aaa** = turns observed **bbb** = turns max **ccc** = window duration, seconds **ddd** = dose count Error log data, if error = 2: **19/000/aaa** **19/bbb/ccc** **19/ddd/eee** **19/fff/ggg** **19/hhh/iii** Where: **aaa** = dose count **bbb/ccc/ddd/eee** = output shaft turns limit, as: bbb * 256 ^ 3 + ccc * 256 ^ 2 + ddd * 256 ^ 1+ eee * 256 ^ 0 (i.e., high byte to low byte, and ^ is exponentiation) **fff/ggg/hhh/iii** = total observed output shaft turns, expressed high byte to low byte as above	Every five seconds, the infusion safety task tests the number of output shaft turns. If the calculated number of turns is more than 25% above the expected number of turns, a service alarm occurs. If this code appears, print out the error log from diagnostic mode.	For **09/018/001** The infuser is delivering at too high a rate due to: V+ regulator fails high motor servo failure software control fault 180 degree miscalibration of the output shaft encoder The indicated rate is above actual rate, due to: spurious transitions on output shaft encoder For **09/018/002** Extra turns were detected, possibly due to: spurious transitions on output shaft encoder software failure to stop motor at end of dose motor start without permission

Table 6-4. Service Alarm Codes - Details

Primary Error (NN)	Supplemental Error (MMM)	Type (TTT)	Error Detection Method	Error Description and Possible Cause
09 MOTOR_ ERROR	**019** MOTOR_ UNDER_ DELIVERY	Error **1** = Too fast **2** = Turns exceeded dose Error log data, if error = 1: **19/pa1/pa2** **19/000/sho** **19/aaa/bbb** **19/ccc/ddd** Where: **pa1** = PACNT_ EXTENDED (high) **pa2** = PACNT_ EXTENDED (low) **sho** = short turns **000** = always zero **aaa** = turns observed **bbb** = turns max **ccc** = window duration, seconds **ddd** = dose count Error log data, if error = 2: **19/pa1/pa2** **19/sho/aaa** **19/bbb/ccc** **19/ddd/eee** **19/fff/ggg** **19/hhh/iii** Where: **pa1** = PACNT_ EXTENDED (high) **pa2** = PACNT_ EXTENDED (low) **sho** = short rev count **aaa** = dose count **bbb/ccc/ddd/eee** = output shaft turns limit, as: bbb * 256 ^ 3 + ccc * 256 ^ 2 + ddd * 256 ^ 1+ eee * 256 ^ 0 (i.e., high byte to low byte, and ^ is exponentiation) **fff/ggg/hhh/iii** = total observed output shaft turns, expressed high byte to low byte as above	Every five seconds, the infusion safety task tests the number of output shaft turns. If the calculated number of turns is more than 25% below the expected number of turns, a service alarm occurs. If this code appears, print out the error log from diagnostic mode.	The infuser is delivering at too low a rate due to: V+ regulator fails low motor servo failure software control fault

Table 6-4. Service Alarm Codes - Details

Primary Error (NN)	Supplemental Error (MMM)	Type (TTT)	Error Detection Method	Error Description and Possible Cause
09 MOTOR_ ERROR	**020** MOTOR_ TAKEOFF	Count of doses begun since the infuser was powered on Error log data: **19/pa1/pa2** **19/obs/sho** Where: **pa1** = PACNT_ EXTENDED (high) **pa2** = PACNT_ EXTENDED (low) **obs** = observed turns (low) **sho** = short revs The infuser counts each rate change as a new dose, except when resuming delivery after a purge, and during TPN ramping.	Every two seconds while the delivery is not in progress, the number of output shaft turns is compared with a limit value which is set whenever a dose stops (the current number of turns plus three). If the number of turns measured exceeds this limit, a service alarm occurs.	Indicated rate is above actual rate due to: spurious transitions on output shaft encoder Motor fails to stop when expected, due to: software control error
10 BEEPER_ ERROR	**000**	**0** indicates digital signal was low and should have been high. **1** indicates digital signal was high and should have been low.	At power on, when non-infusion safety task is initiated, a check is performed to determine if the beeper is emitting sound. If the signal is high when the beeper should be off or low; or when the beeper should be on, a service alarm is activated.	An incorrect digital signal could indicate that the beeper is not functioning properly or that the circuitry designed to check the beeper is malfunctioning.
11 POWER_ SENSING_ ERROR	**000** OVERVOLT_ 5V	ADC 5 V input reading	The 5V line is tested at power on and once each second. If the voltage is greater than expected, a service alarm occurs.	More than 5.5 volts measured on the 5 V line due to: 5 V regulator failure power sensing circuitry failure
	001 UNDERVOLT_ 5V	ADC 5 V input reading	The 5 V line is tested at power on and once each second. If the voltage is less than expected a service alarm occurs.	Less than 4.5 volts measured on the 5 V line due to: 5 V regulator failure power sensing circuitry failure

Table 6-4. Service Alarm Codes - Details

Primary Error (NN)	Supplemental Error (MMM)	Type (TTT)	Error Detection Method	Error Description and Possible Cause
11 POWER_ SENSING_ ERROR	**002** OVERVOLT_ ALK	ADC battery compartment input reading	The AA battery input line is tested at power on and once each second. If the voltage is greater than expected, a service alarm occurs.	More than 3.2 volts measured on the battery voltage input due to: improper type of batteries installed
	003 OVERVOLT_ EXT	ADC external power input reading	The external power input line is tested at power on and once each second. If the voltage is greater than expected, a service alarm occurs.	More than 3.6 volts measured on the external input due to: power sensing circuitry failure
	004 NO_LITHIUM	ADC lithium input reading	The lithium battery input line is tested at power on and once each second. If the voltage is less than expected, a service alarm occurs.	Less than 2 volts measured on the lithium battery input due to: lithium battery discharged lithium battery output shorted
12 STUCK_KEY	N/A	Key value	At power on the keypad is scanned. If a key is active, an error message is displayed. If the key continues to be active for more than one minute, a service alarm occurs. The keypad ISR scans for key presses and tests each read against the previous one. If a key is active continuously for more than one minute, a service alarm occurs.	A stuck key press was detected due to: keypad failure

Table 6-4. Service Alarm Codes - Details

Primary Error (NN)	Supplemental Error (MMM)	Type (TTT)	Error Detection Method	Error Description and Possible Cause
13 TIME_BASE_ ERROR	**000**	Number of RTIs counted	The number of elapsed RTIs is tested once each second. If the number is within the expected range, the count is zeroed. If the number is not within the expected range, a service alarm occurs.	Timing error due to: oscillator failure RTI failure
	001	Number of RTIs counted	The number of elapsed RTIs is incremented and tested once each RTI. If the number exceeds the upper limit value since the last one second interrupt, a service alarm occurs.	Timing error due to: oscillator failure clock chip failure IRQ interrupt failure

Table 6-4. Service Alarm Codes - Details

Primary Error (NN)	Supplemental Error (MMM)	Type (TTT)	Error Detection Method	Error Description and Possible Cause
14 WATCHDOG_ ERROR	**001**	Reading of PACNT	At power on, the watchdog PIC is tested by overstrobing it while trying to run the motor. If the motor moves more than 20 counts, a service alarm occurs.	Watchdog PIC circuit is not functioning, due to: PIC being in its disabled mode PIC failure fault in connection between PIC and motor power regulator SHDN pin motor is being moved by pushing on plunger during PIC test
	003	Task number **1** = Infusion safety **2** = Non-infusion safety **3** = Pressure **4** = Motor **5** = Display manager **6** = Not used **7** = Keypad **8** = Infusion	Various periodic tasks update progress counters to indicate that they are still running. Other periodic tasks check those counters and count the number of checks that have gone by without a change in the counter. When the number of checks without change exceeds 20, a service alarm occurs.	A periodic task has stopped updating its counter, due to: RAM corruption or error task deadlock programming error

Table 6-4. Service Alarm Codes - Details

Primary Error (NN)	Supplemental Error (MMM)	Type (TTT)	Error Detection Method	Error Description and Possible Cause
15 POWER_ DOWN_ ERROR	N/A	System state **0** = Power on **1** = Normal operation **3** = Service alarm **4** = Power off **5** = Power down started	At power on the system state is tested. If power down processing is completed, power on processing continues. If the system began power down processing, but did not complete it, a service alarm message is logged to the history and processing is allowed to continue. If the power down processing did not start, a service alarm occurs.	The infuser did not perform normal power down processing due to: hardware reset
16 SOFTWARE_ ERROR	**001** INVALID_ STATE	**0**	The infusion safety task tests the air-in-line alarm status when it receives a start or restart command. If the alarm is already active, a service alarm occurs.	The air-in-line was active when it should not be due to: RAM chip failure Bus failure
	002 KEY_EVENT_ TIMEOUT	Task ID	The callback functions failed to send an acknowledgement message to the IED task within 6 seconds after receiving a key-event.	Tasks are in deadlock condition
	003 INVALID_ ALARM_ SEMAPHORE	Semaphore value	The alarm task verifies semaphore values when received. If processing is not defined for a semaphore value, a service alarm occurs.	The alarm task received an invalid alarm semaphore value due to: RAM chip failure Bus failure

Table 6-4. Service Alarm Codes - Details

Primary Error (NN)	Supplemental Error (MMM)	Type (TTT)	Error Detection Method	Error Description and Possible Cause
16 SOFTWARE_ ERROR	**004** INVALID_ ALARM_ MESSAGE	Action value	The alarm task verifies actions requested when a mailbox message is received. If processing is not defined for an action value, a service alarm occurs.	The alarm task received an invalid alarm action request due to: RAM chip failure Bus failure
	005 INVALID_ ALARM_TYPE	Alarm type value	The alarm task verifies alarm types requested when a mailbox message is received, when alarms are logged to the history, and when an alarm status is requested. If the alarm type received is invalid, a service alarm occurs.	The alarm task received an invalid alarm type due to: RAM chip failure Bus failure
	006 INVALID_ ALARM_ CALLBACK	Callback ID	The alarm task verifies callback IDs when a key press is passed to the alarm callback processing function. If the callback ID is invalid, a service alarm occurs.	An invalid alarm callback type was requested due to: RAM chip failure Bus failure
	007 INVALID_ SOUND_TYPE	Sound type value	The audible alarm processing functions that start and stop sounds verify the values passed to them. If an invalid sound type is requested a service alarm occurs.	An invalid sound type was requested due to: RAM chip failure Bus failure
	008 IQUEUE_FULL	Queue # **0** = Air in **1** = Air out **2** = Pressure in **3** = Pressure out **4** = Motor in **5** = Motor out **6** = Infusion safety in **7** = Keypad out	When the queue processing function receives a request to add data to a queue, it verifies that there is space available in the queue. If the queue is full, a service alarm occurs.	A request was received to add data to a queue that was already full due to: CPU overload software control fault receiving task unresponsive

Table 6-4. Service Alarm Codes - Details

Primary Error (NN)	Supplemental Error (MMM)	Type (TTT)	Error Detection Method	Error Description and Possible Cause
16 SOFTWARE_ ERROR	**009** ISA_INVALID_ MSG	**0**	When the infusion safety task receives an unrecognizable message code, a service alarm occurs.	The infusion safety task received an invalid message type due to: RAM chip failure Bus failure
	010 ISA_NULL_MSG	**0**	When RTXC passes a NULL message to the infusion safety task, a service alarm occurs.	The infusion safety task received a null message type due to: RAM chip failure Bus failure
	011 ISA_INVALID_ PRESSURE	Message data value	The infusion safety task checks the pressure message type code when received. If it is not a recognized value, a service alarm occurs.	The infusion safety task received an invalid pressure message due to: RAM chip failure Bus failure
	012 ISA_EMPTY_ IQUEUE	Queue # **0** = ISA_AIR_ADC **1** = ISA_PRESS_MSG2 **2** = ISA_PRESS_ADC **3** = ISA_NO_MSG	The infusion safety task reads from queues when processing the ISR semaphore. If the air and pressure queues are empty or if a check cassette message was received without a type value, a service alarm occurs.	The infusion safety task did not receive expected queue information due to: software error RAM chip failure Bus failure
	013 ISA_BAD_ SEMAPHORE	**0**	The infusion safety task verifies semaphore values when received. If processing is not defined for a semaphore value, a service alarm occurs.	The infusion safety task received an invalid semaphore value due to: RAM chip failure Bus failure
	014 ISA_INVALID_ AIR	Message data value	The infusion safety task verifies air message data when received. If processing is not defined for an air message value, a service alarm occurs.	The infusion safety task received an invalid air message due to: RAM chip failure Bus failure

Table 6-4. Service Alarm Codes - Details

Primary Error (NN)	Supplemental Error (MMM)	Type (TTT)	Error Detection Method	Error Description and Possible Cause
16 SOFTWARE_ ERROR	**015** ISA_BAD_CK_ CASS_CODE	Bad check cassette code	The infusion safety task verifies check cassette message data when received. If processing is not defined for a check cassette message, a service alarm occurs.	The infusion safety task received an invalid check cassette message due to: RAM chip failure Bus failure
	016 ISA_BAD_ RESUME	**0**	The infusion safety task verifies that a prior START message has been received when it receives a RESUME message. If this is not the case, a service alarm occurs.	software error RAM error
	017 ISA_RATE_ MISMATCH	**0** = ITD_NO_DELIVERY **1** = ITD_TAPER_UP **2** = ITD_TAPER_DOWN **3** = ITD_CONTINUOUS **4** = ITD_BOLUS **5** = ITD_LOAD_DOSE **6** = ITD_PURGE **7** = ITD_PIGGYBACK **8** = ITD_KVO **9** = ITD_AUTOKVO **10** = ITD_PHASE **11** = ITD_BASE_RATE **12** = ITD_INTERMITTENT Error log data: **20/aaa/bbb** **20/ccc/ddd** **20/aaa/bbb** **20/ccc/ddd** Where: **aaa/bbb** = isafety rate, as 256 * aaa + bbb **ccc/ddd** = infusion task rate, as 256 * ccc + ddd	Every two seconds, a structure containing the infuser's rate and other data is cross-checked against the rate contained in the infusion safety task. If these rates do not match for eight consecutive samples, a service alarm occurs. If this code appears, print out the error log from diagnostic mode.	software error RAM error

Table 6-4. Service Alarm Codes - Details

Primary Error (NN)	Supplemental Error (MMM)	Type (TTT)	Error Detection Method	Error Description and Possible Cause
16 SOFTWARE_ ERROR	**018** ISA_MODE_ MISMATCH	0xy **x** = infusion task's infusing flag (1 = yes, 0 = no) **y** = value of GLOBAL_ MAIN_MODE **1** = PROGRAMMING _MODE **2** = REVIEW_MODE **3** = STOP_MODE **4** = RUN_MODE **5** = CHANGE_MODE **6** = OPTIONS_MODE **7** = MAX_MODE_TYPES	Every two seconds, the variables, GLOBAL_MAIN_ MODE and PUMP_INFUSING are compared for consistency. If three samples in succession are not consistent, a service alarm occurs.	software error RAM error
	020 REMOTEQ_ OUT_ FULL	**1** = Remote queue for the output message is full	When a message needs to be stored at the end of the outgoing message queue and the queue is full, a service alarm occurs.	software error RAM error flow rate of the outgoing messages is too slow
	021 REMOTEQ_ OUT_ EMPTY	**1** = Remote queue for the outgoing message is empty	When the SCI_OUTPUT task is attempting to send an outgoing message to the serial port, or attempting to free a message from an empty queue, a service alarm occurs.	software error RAM error
	022 REMOTEQ_ OUT_BAD_ STATE	**1** = Remote queue for the outgoing message is in bad state	When a message needs to be stored at the end of the outgoing message queue and it is in a bad state, a service alarm occurs.	software error RAM error
	023 ISA_BAD_ RATE	**1** = Taper overrate error **2** = Standard delivery overrate error	If a tapered rate is greater than 450 mL/hr or a non-tapered rate is greater than 1000 mL/hr, a service alarm occurs.	software error RAM error

Table 6-4. Service Alarm Codes - Details

Primary Error (NN)	Supplemental Error (MMM)	Type (TTT)	Error Detection Method	Error Description and Possible Cause
16 SOFTWARE_ ERROR	**024** INVALID_TIME_ IN_ SECONDS	**0**	If the infuser has a program in it and has the time set such that the infuser rolls over from 2004 to 2005, the service alarm occurs and the current program is erased. If the infuser is on at midnight, January 1, 2005, the alarm will occur immediately. If the infuser is off at midnight January 1, 2005, the next time it is on it will alarm.	Infuser clock rolls over from 2004 to 2005
18 HISTORY_ PTR_ERROR	**000** WRITE_HLOG_ ERROR	**xxx**: debug information	Each time a record is written to the history, the history pointers are tested. If the pointers are not within the accepted limits, a service alarm occurs.	History pointers became corrupted due to: RAM chip failure Bus failure
	001 TRAVERSING_ TO_BOTTOM_ ERROR	**xxx**: debug information	Each time the GET_PREV_ HRECORD ( ) is called, the top and bottom pointers are checked to assure the pointers are pointing in the ranges as expected.	History pointers became corrupted due to: RAM chip failure Bus failure
	002 TRAVERSING_ TO_ TOP_ERROR	**xxx**: debug information	Each time the GET_NEXT_ HRECORD ( ) is called, the top and bottom pointers are checked to assure the pointers are pointing in the ranges as expected.	History pointers became corrupted due to: RAM chip failure Bus failure
21 COMM_ ERROR	**000** IN_BUF_ERR	**000** MAX_OVERRUNS_ EXCEEDED	When SCI interrupt attempts to add a byte to a full data buffer, a service alarm occurs.	Data communication error

Table 6-4. Service Alarm Codes - Details

Primary Error (NN)	Supplemental Error (MMM)	Type (TTT)	Error Detection Method	Error Description and Possible Cause
21 COMM_ ERROR	**000** IN_BUF_ERR	**001** REMOTE_INPUT_ QUEUE_ EMPTY	When SCI input task attempts to extract data from an empty incoming message queue, a service alarm occurs.	Data communication error
	002 IN_MSG_ERR	**004** BAD_KEY_MSG	When SCI input task receives an unknown key-event, a service alarm occurs.	Data communication error
	002 IN_MSG_ERR	**005** BAD_MSG_TYPE	When SCI input task receives an unknown message type, a service alarm occurs.	Data communication error
	002 IN_MSG_ERR	**006** BAD_SESS_RQST	When SCI input task receives a bad session request message, a service alarm occurs.	Data communication error

6.4
OPERATIONAL ALARMS

Table 6-5, Operational Alarms, lists operational alarms, formats, descriptions, possible causes, and corrective actions.

Table 6-5. Operational Alarms

Operational Alarm	Format	Description/Possible Cause/Corrective Action
Air-in-Line	**nnn**	**nnn** represents the signal being read by the air sensor. The expected reading for a well-seated cassette ranges from 80 to 180. Readings in the 50–80 range can signify one of the following: There is a buildup of fine bubbles near the outlet of the cassette where the air sensor is located. The distal tube has been partially pulled out of its position between the pincers of the air sensor. There is air in the tube and the outside of the tube is wet. Very low readings (1–5) are usually caused by air-in-line, but can also be caused by pulling very hard on the distal tube. A reading of zero indicates either air in the tube or a broken sensor. If a primed set is loaded in the infuser and air alarms occur with a reading of zero, replace the sensor.
Check Cassette	**P nnn**	**nnn** above 150 signifies high pressure upstream and can signify one of the following: Fluid was injected with a syringe into an upstream Y-site and there is a backcheck valve in place. Fluid must be injected slowly (i.e., at the delivery rate or less). User pressed syringe during delivery. Use Hospira recommended syringe sizes, and use a syringe adapter for very small-bore syringes. The infuser was pumping near maximum rate with the container more than two feet above the infuser, which can produce large increases in the inlet pressure. Lower the container or reduce the rate. The outside of the cassette has a sticky build-up in its pressure sensing hole. Assure the part of the cassette that faces the infuser is free of debris and sticky or dried liquids. Confirm the pocket in which the cassette fits is reasonably clean. **nnn** below 90 indicates the cassette has been fully or partly unlatched. Confirm the cassette is fully snapped in at both ends.
Check Cassette	**D nnn**	The distal pressure sensor has detected a condition indicating that the cassette is not properly latched at the outlet end. Confirm the cassette is fully snapped in at both ends.

Table 6-5. Operational Alarms

Operational Alarm	Format	Description/Possible Cause/Corrective Action
Check Cassette	**A nnn**	**nnn** represents the signal being read by the air sensor. When this alarm occurs, the number should be above 180, and can signify one of the following: The tubing by the sensor has been flattened by using the set for a long time or in high temperatures. Tugging on the distal line will often relieve the problem. The tubing by the sensor is wet on the outside, making accurate readings difficult. Confirm the tubing is reasonably dry.
Proximal Occlusion	**nnn**	The inlet pressure is not high enough to allow delivery, signifying one of the following: The inlet tubing may be clamped. The valve on a ball check set or burette set may be closed. A syringe may be stuck. **nnn** is used to track cassette performance, and does not provide any information to help determine the source of the problem.
Distal Occlusion	**nnn**	The outlet pressure is too high, signifying one of the following: The outlet tube is clamped or a manifold valve is closed. The patient line is restricted. Check for kinks and clots. The distal occlusion setting is too low for the infuser or fluid in use. A filter, narrow-bore tubing, thick fluid, or a fine gauge needle can elevate distal pressure at the infuser. This alarm can also be caused by pumping into an elevated patient. Use a higher pressure setting, reduce the restrictions, or lower the delivery rate.
Switch to Batteries	**nnn**	**nnn** is the ADC value measured by the infuser.
Low Batteries	**nnn mmm**	**nnn** is the internal ADC value measured by the infuser. **mmm** is the external ADC value measured by the infuser.
Power Loss	**H** or **S**	**H** if the power loss was initiated by the hardware **S** if the power loss was initiated by the software

Section 7

REPLACEABLE PARTS AND REPAIRS

The GemStar has no user-serviceable components, with the exception of disposable batteries.

Infuser disassembly and assembly is performed only by Hospira certified technicians. *Figure 7-1, GemStar Infuser Exploded view*, is provided for reference only.

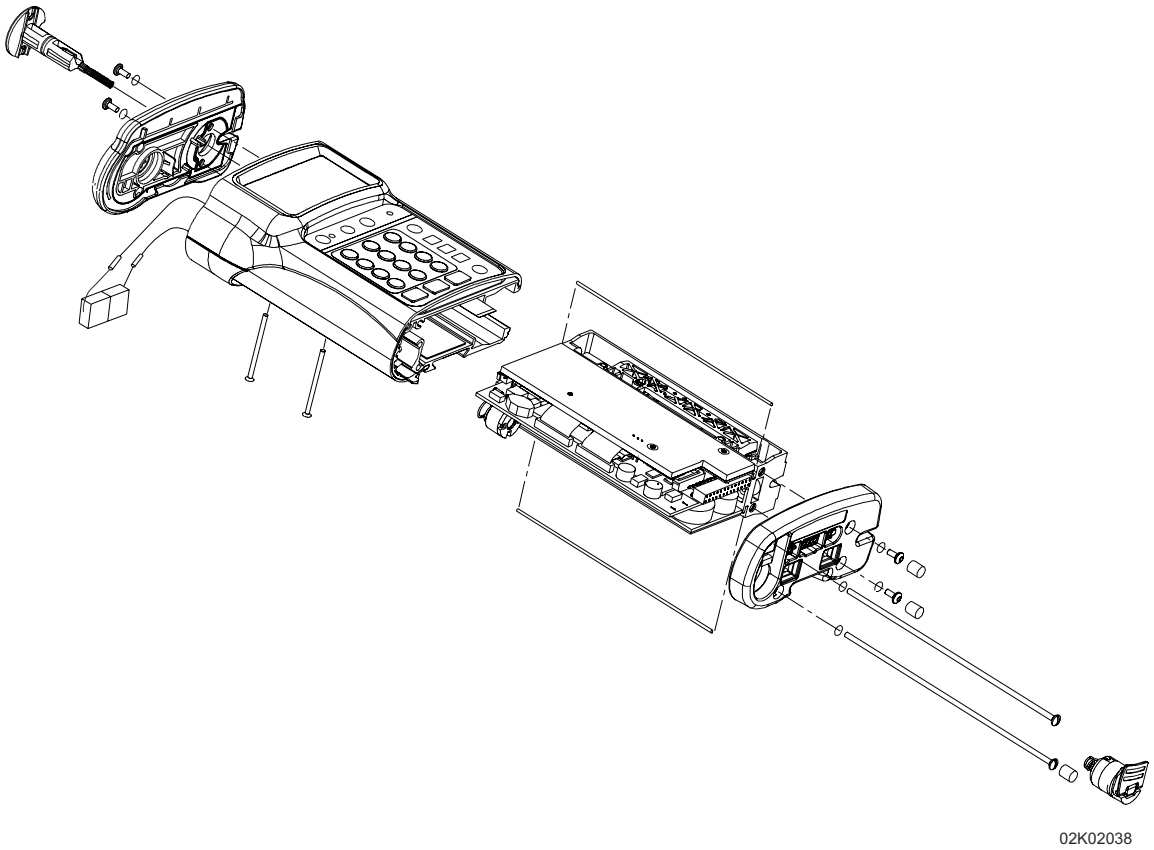

Figure 7-1. GemStar Infuser Exploded view

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Section 8

SPECIFICATIONS

The following specifications apply to the GemStar infuser.

PHYSICAL

Dimensions: Height: 5.5 in. (14.0 cm)
Width: 3.8 in. (9.7 cm)
Depth: 2.0 in. (5.1 cm)

Weight: Approximately 17 oz. (482 grams) excluding batteries

TRANSPORT AND STORAGE ENVIRONMENT Store in cool and dry environment

Ambient Temperatures: -4 to +140 F (-20 to +60 C)

Relative Humidity: 10% to 90%; non-condensing

OPERATING ENVIRONMENT

Ambient Temperatures: +41 to +104 F (+5 to +40 C)

Relative Humidity: 10% to 90%; non-condensing

Atmospheric Pressure: 0 - 10,000 ft. (0 - 3,000 m) equivalent pressure

POWER SOURCES

AC Mains: Wall-mount AC mains adaptor;
6 ft. (1.8 m) cord; molded plug
Input: 110 V_{AC}
Output: 3.0 V_{DC}

Tabletop AC mains adaptor;
molded plug
Input: 100 - 240 V_{AC}
Output: 3.0 V_{DC}

Battery: Two disposable AA, or lithium

Battery Pack: Rechargeable using GemStar AC mains adaptor

POWER CAPACITY Using two fresh, disposable AA batteries or a charged battery pack, at room temperature, the infuser is capable of delivering approximately:

96 hours at rates below 5 mL/hr

48 hours at rates at or above 5 mL/hr but below 25 mL/hr

24 hours at rates at or above 25 mL/hr but below 125 mL/hr

3000 mL at a rate of 125 mL/hr or higher

PUMP MECHANISM	Volumetric; piston driven
MEMORY PROTECTION	Current program and 400-event history log protected by internal lithium battery-backed memory for at least one year after power is removed
OPERATING CONTROLS	One 23-key keypad Bolus, data port, and AC mains jacks Bolus button
EXTERNAL POWER LED	Green LED marked with plug icon illuminates continuously when the infuser is connected to AC mains Green LED blinks when the infuser is connected to external batteries
ALARM LED	Red LED marked with alarm icon illuminates continuously for self-test error alarm conditions Red LED blinks during all alarm conditions which are user-recoverable
AUDIBLE ALARM	The audible alarm is user-adjustable from the maximum volume down to silent The alarm automatically reverts to the maximum volume if the user does not respond within one minute
DISPLAY	Backlit, four-line-by-sixteen-character alphanumeric graphics display
Backlight on AC:	Continuous
Backlight on Batteries:	Continuous during programming, program review, and history display; otherwise activated by keypress or alarm; not activated by bolus request
REAL-TIME CLOCK	Accuracy of ± 1 minute per month or better
PRINT FUNCTION	
Port and Interface:	RS-232 serial interface port; minimum baud rate of 2400; isolated circuit
Printers:	Seiko™ DPU 414 or compatible serial printer
SYSTEM ACCURACY	± 10% for rates of 0.1 to less than 5 mL/hr ± 5% for rates of 5 to 1000 mL/hr

AIR SENSITIVITY

ON: Infuser alarms at approximately 0.5 mL of air

Alarms for any bubble greater than 500 microliters with a tolerance of 200 microliters

2 mL: Infuser alarms at approximately 2 mL of air

Alarms when infuser detects 2.0 +1.0/-0.2 mL of air in 6 mL of total volume delivered

OFF: Alarm is not activated

OCCLUSION SENSITIVITY

Distal Occlusion

Low: Alarms when infuser detects distal pressure greater than 7 psi (48 kPa) ± 5 psi (± 34 kPa)

Medium: Alarms when infuser detects distal pressure greater than 12 psi (83 kPa) ± 8 psi (± 55 kPa)

High: Alarms when infuser detects distal pressure greater than 26 psi (179 kPa) + 14 psi (+ 96 kPa)

Proximal Occlusion: Alarms when infuser detects proximal pressure less than or equal to -4 psi (-28 kPa)

PIGGYBACK RATE 0.1 - 300 mL per hour

INFUSER SELF TESTS AND SAFETY FEATURES Self test performed when the power switch is activated

Diagnostic routine, including motor speed and air-detection monitoring, is repeated continuously while the infuser is powered on

Error and alarm conditions are indicated by both audible and visual alarms; delivery in progress is stopped, if appropriate

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Section 9
DRAWINGS

Figure 9-1 through *Figure 9-4* show the PWA schematic diagrams. *Table 9-1* lists drawings by figure number, title, and part number.

Note: Drawings and schematics in *Section 9* are provided as information only. Drawings and schematics may not exactly reflect current product configuration.

Table 9-1. Drawings

Figure No.	Title	Part Number
9-1	GemStar Boards	102665
9-2	GemStar Top Board (2 Sheets)	
9-3	GemStar Middle Board (3 Sheets)	
9-4	GemStar Bottom Board (3 Sheets)	

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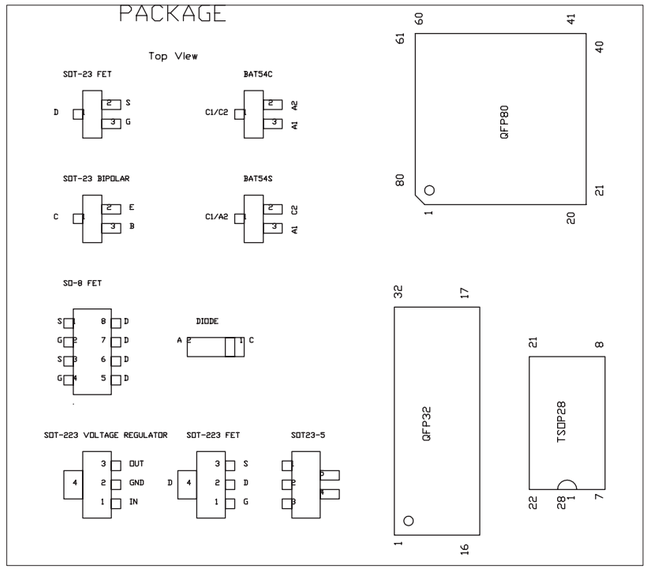
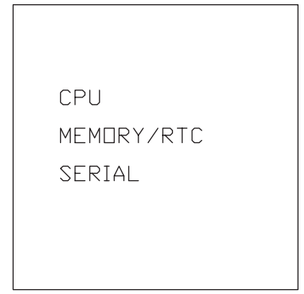
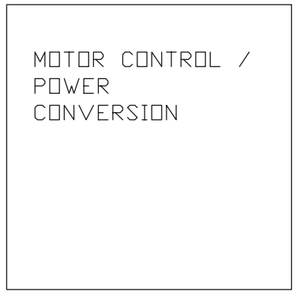
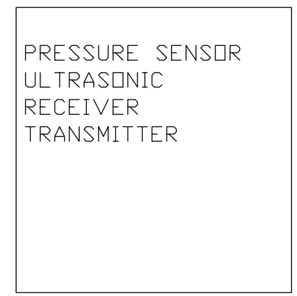




TOP BOARD
TOP

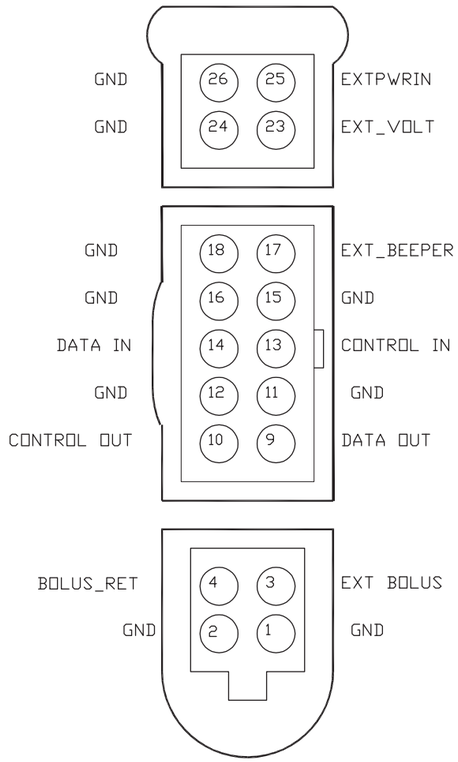


MIDDLE BOARD
MIDDLE



BOTTOM BOARD
BOTTOM

PUMP BOTTOM VIEW
CONNECTOR PIN OUT



HOSPIRA, INC.	
Figure 9-1. GemStar Boards	
DRAWING NO. 102665	Rev. E
	Sheet 1 of 1

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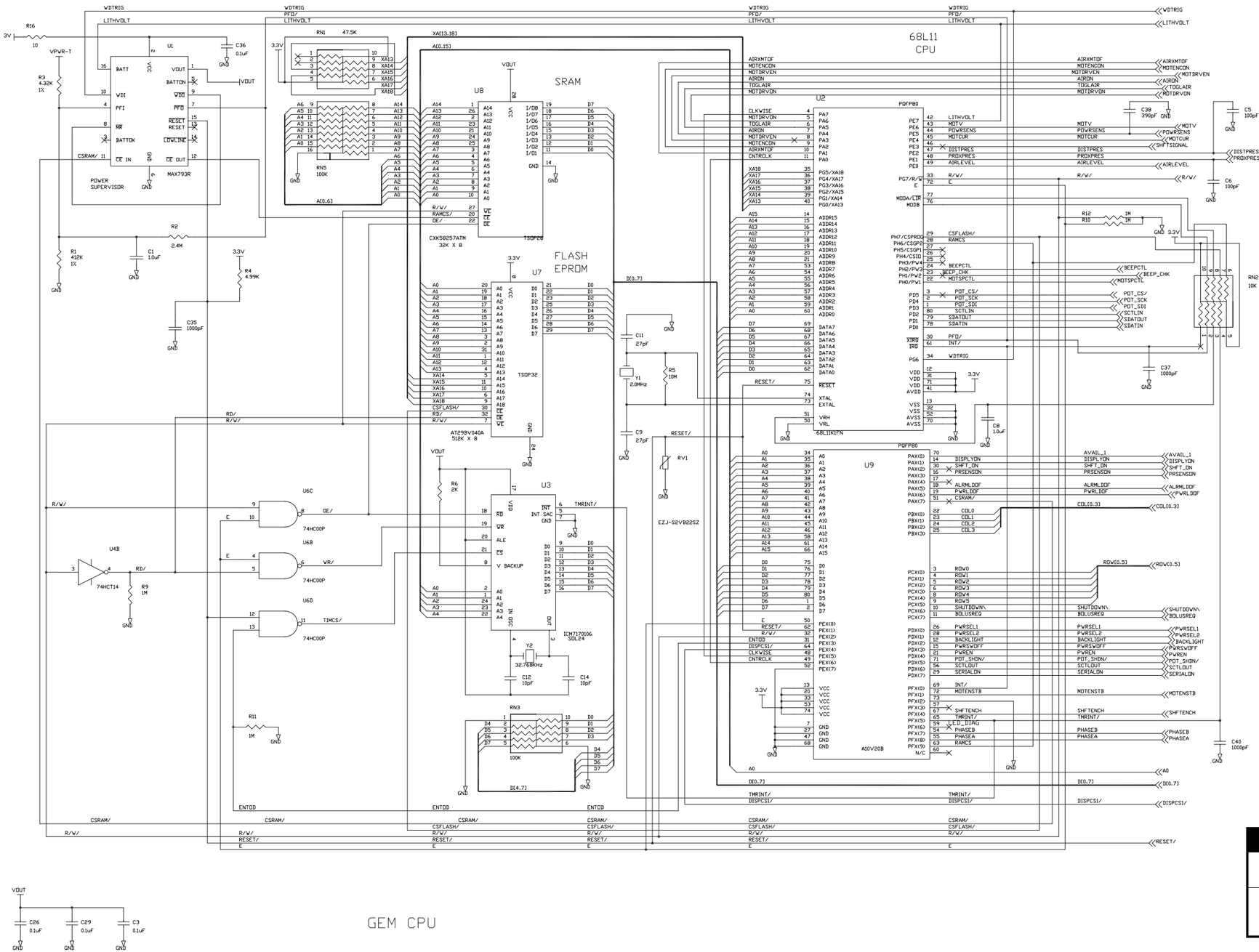

GEM CPU

HOSPIRA, INC.	
Figure 9-2. GemStar Top Board	
DRAWING NO. 102665	Rev. E
	Sheet 1 of 2

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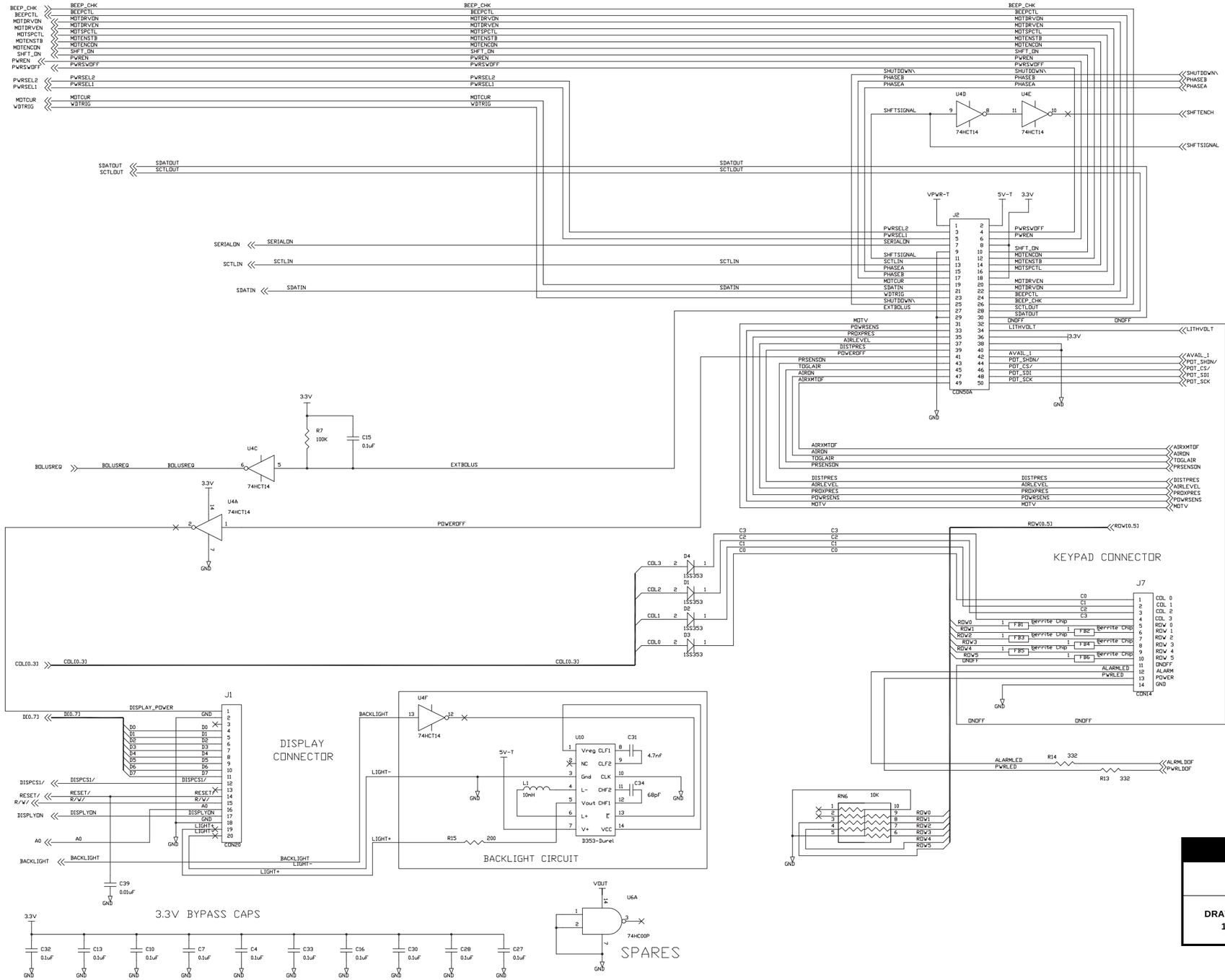

HOSPIRA, INC.	
Figure 9-2. **GemStar Top Board**	
DRAWING NO. **102665**	**Rev. E**
	Sheet 2 of 2

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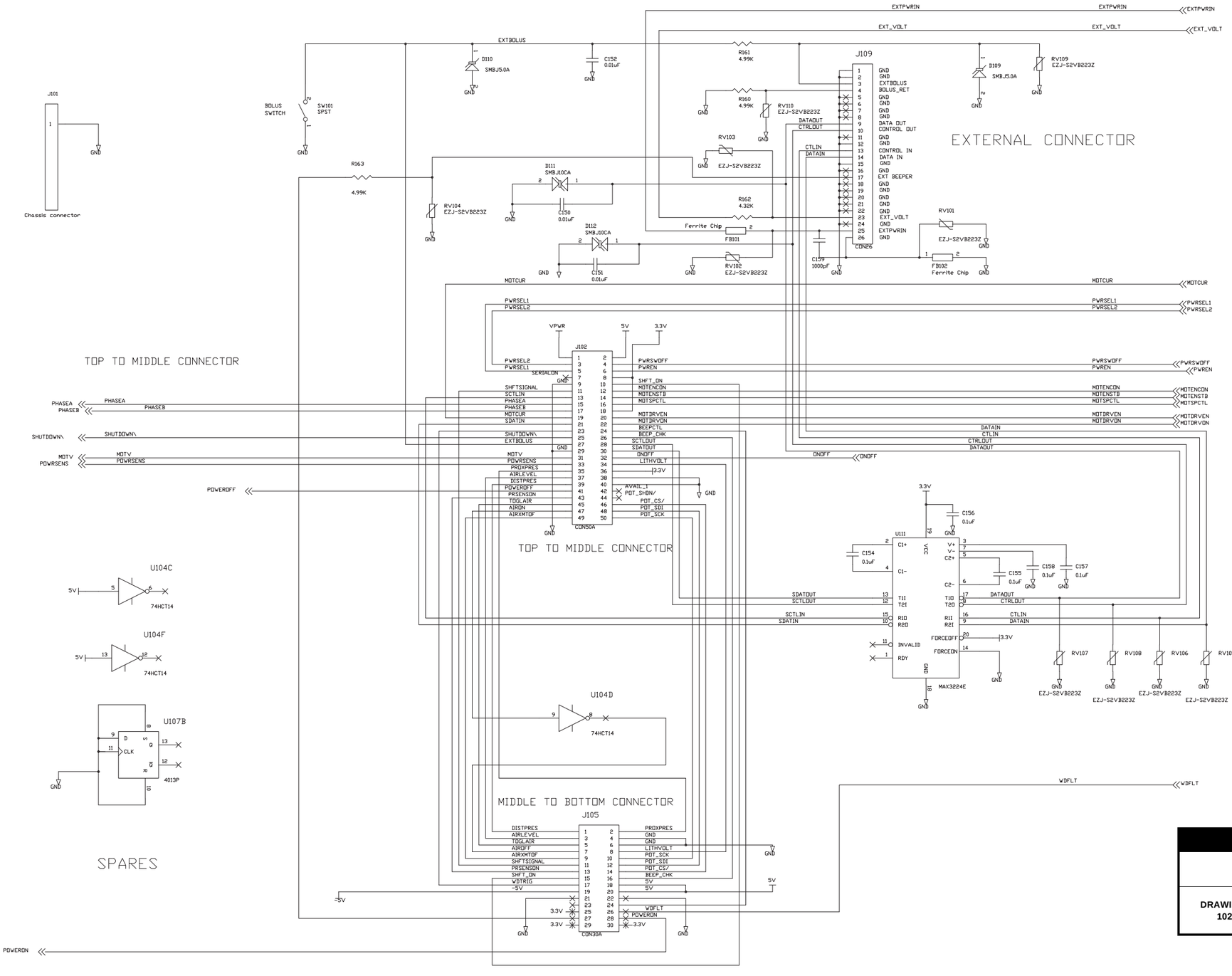

HOSPIRA, INC.	
Figure 9-3. GemStar Middle Board	
DRAWING NO. 102665	Rev. E
	Sheet 1 of 3

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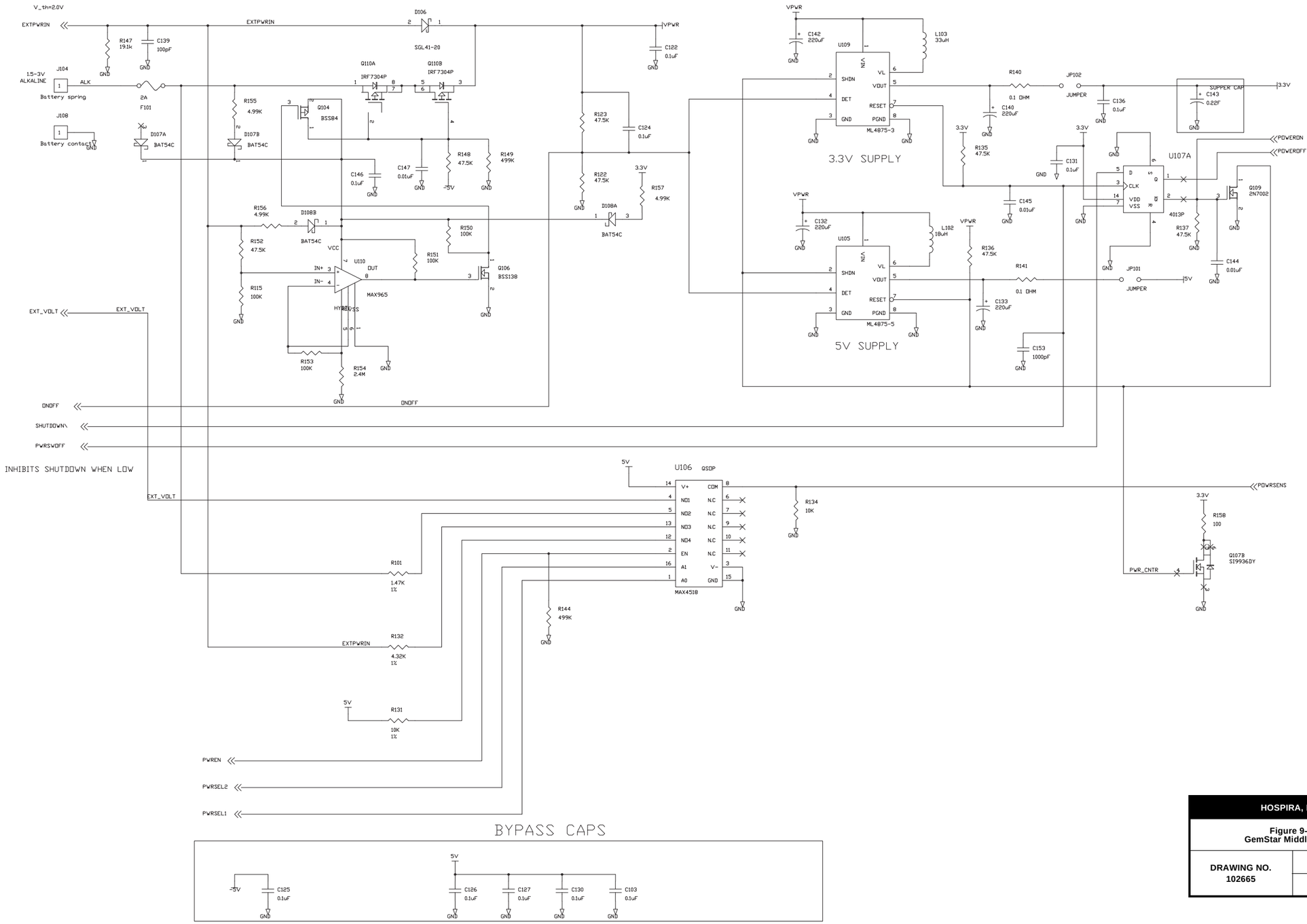

HOSPIRA, INC.	
Figure 9-3. GemStar Middle Board	
DRAWING NO. 102665	**Rev. E**
	Sheet 2 of 3

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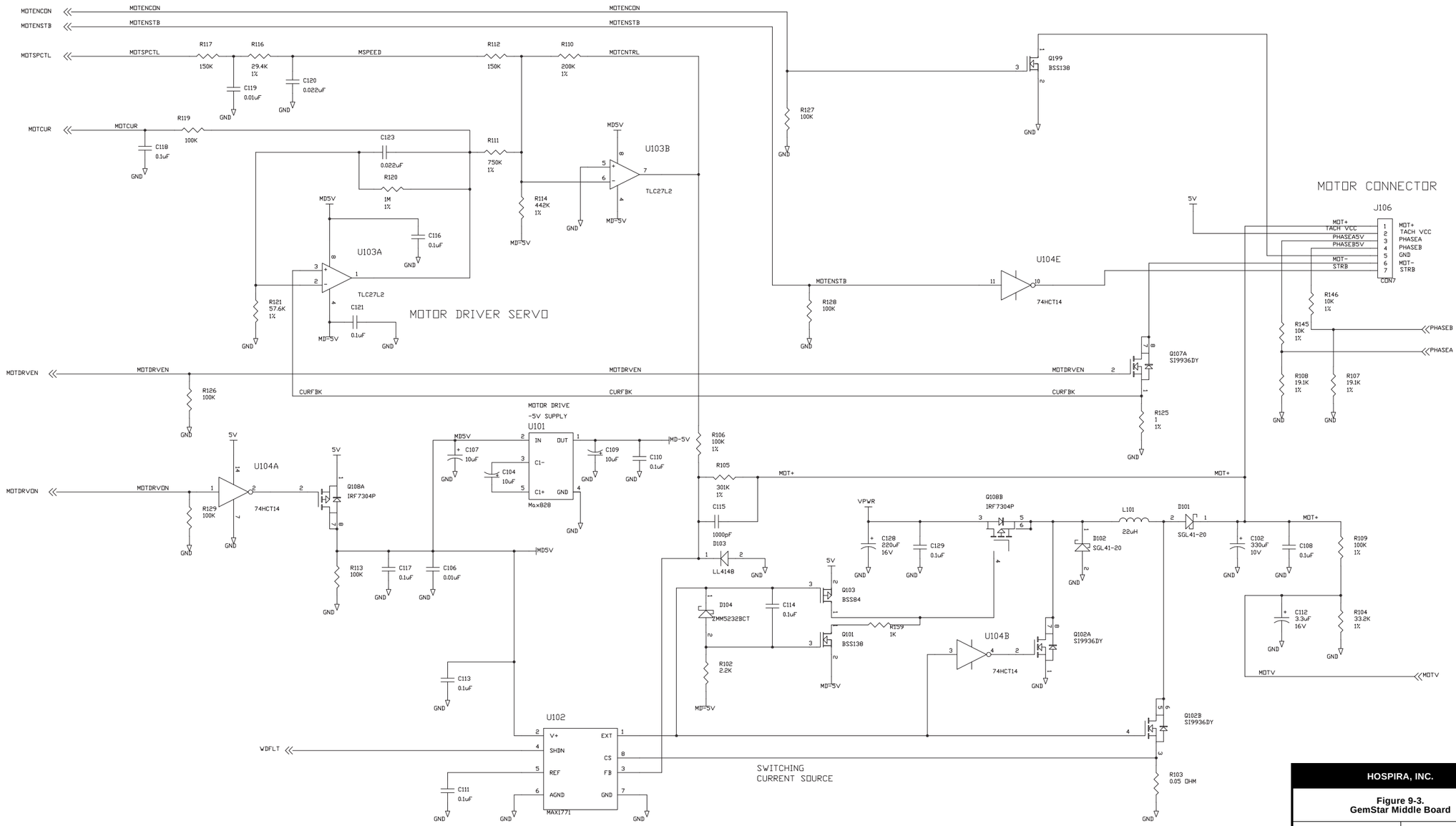

MOTOR DRIVER SERVO

HOSPIRA, INC.	
Figure 9-3. **GemStar Middle Board**	
DRAWING NO. **102665**	**Rev. E**
	Sheet 3 of 3

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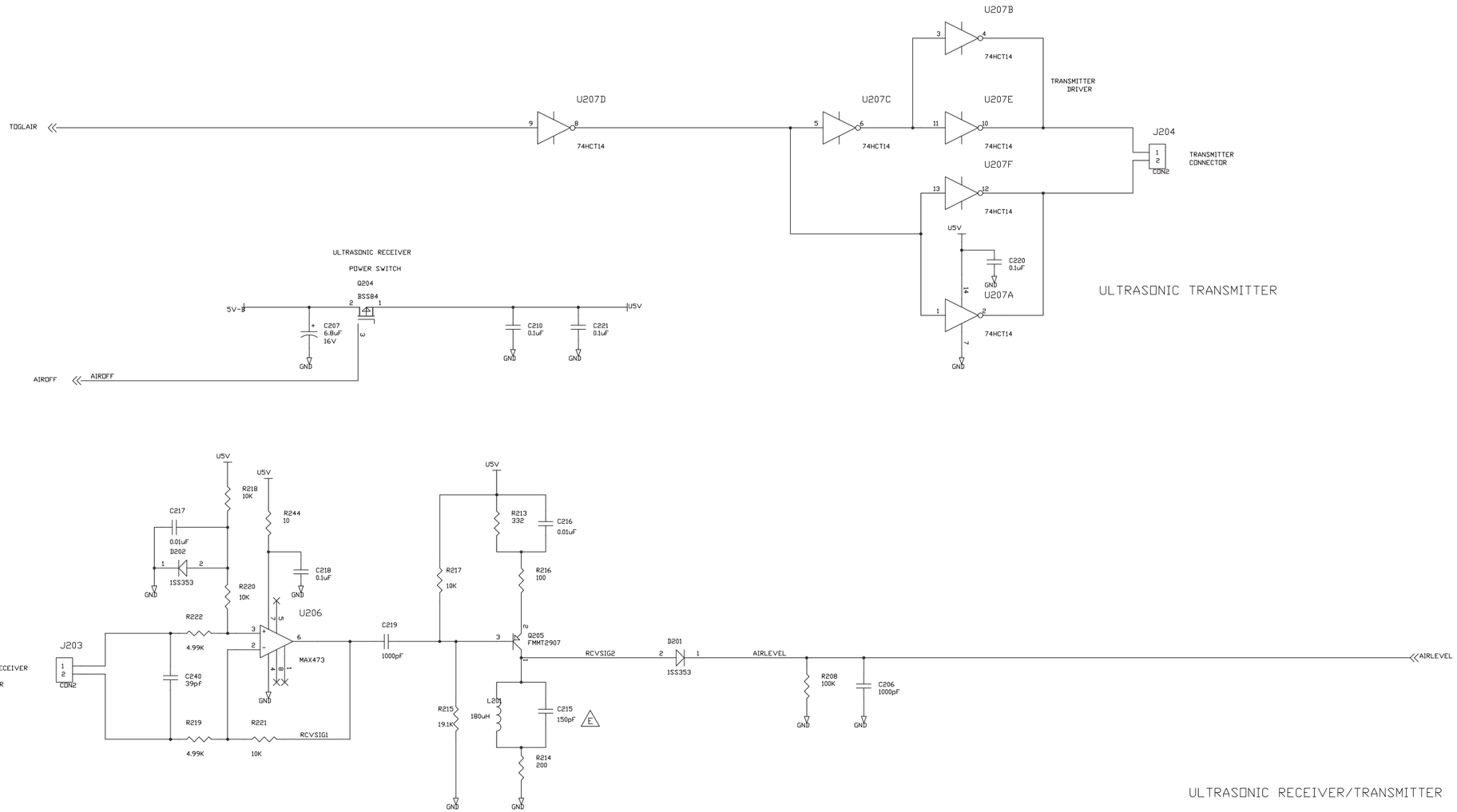

HOSPIRA, INC.	
Figure 9-4. **GemStar Bottom Board**	
DRAWING NO. **102665**	**Rev. E**
	Sheet 1 of 3

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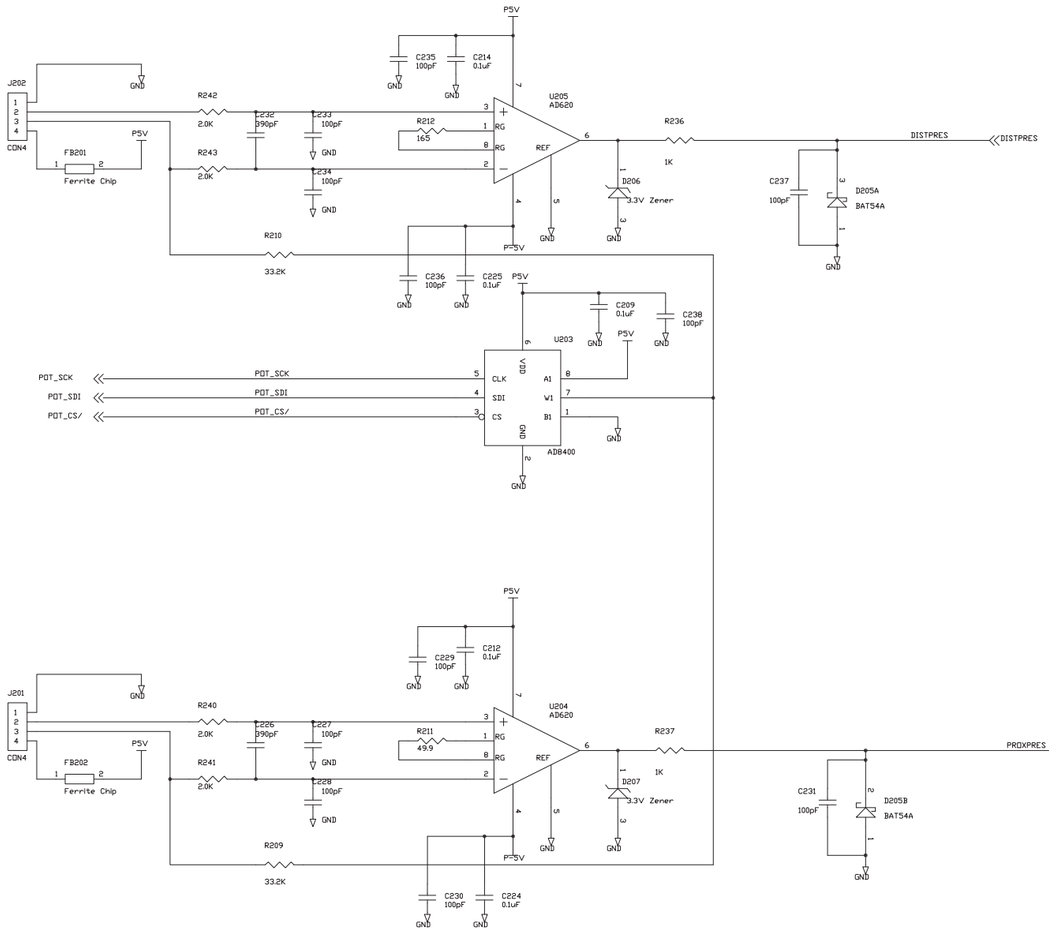

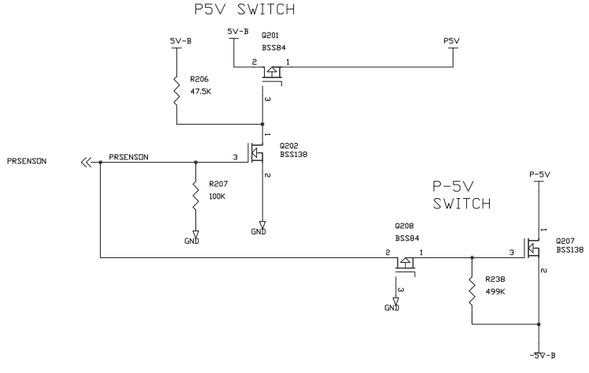

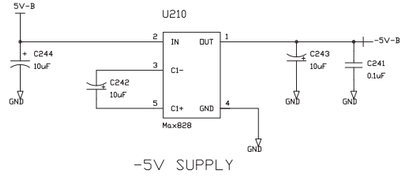

PRESSURE SENSOR INTERFACE

HOSPIRA, INC.	
Figure 9-4. GemStar Bottom Board	
DRAWING NO. 102665	Rev. E
	Sheet 2 of 3

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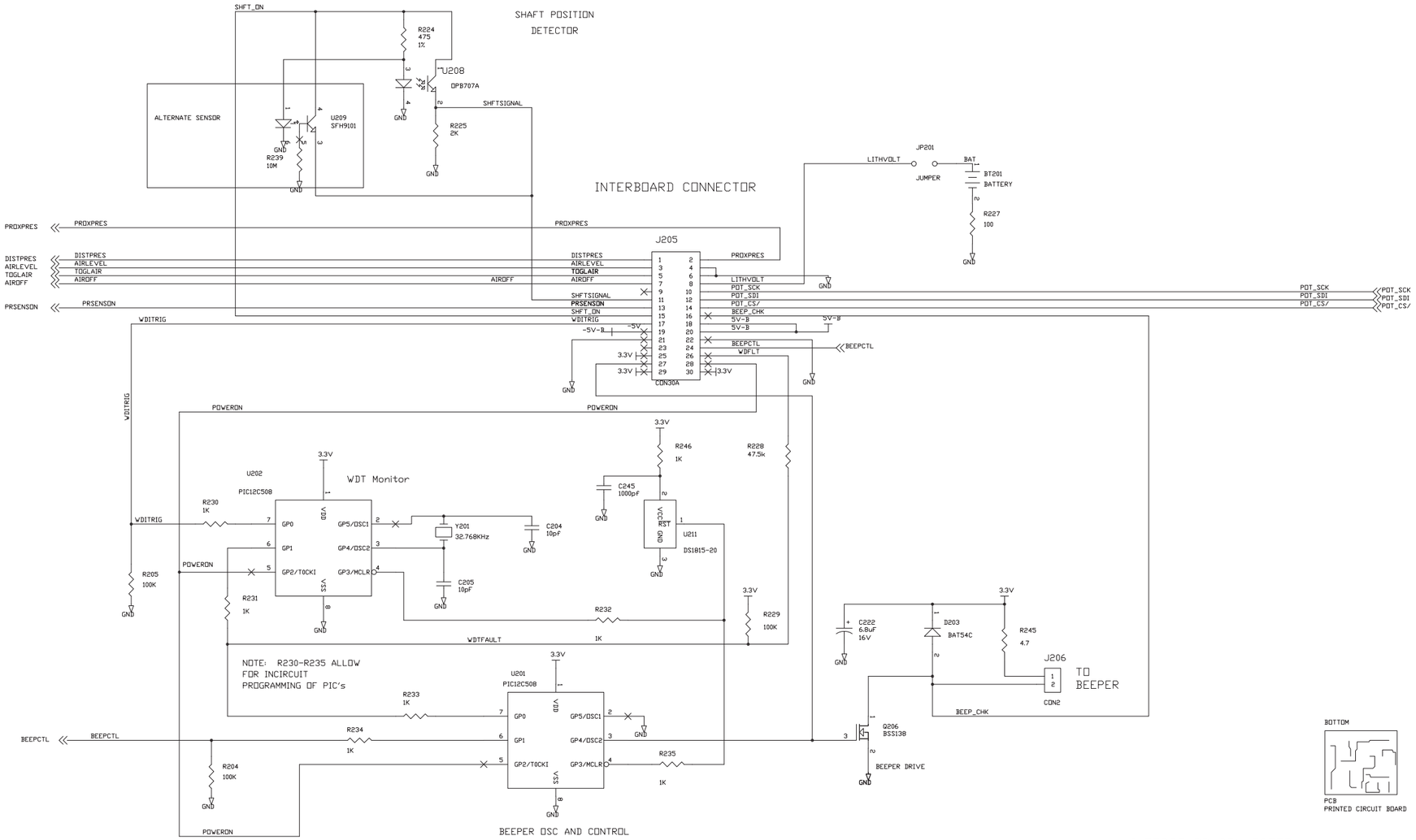

HOSPIRA, INC.	
Figure 9-4. GemStar Bottom Board	
DRAWING NO. 102665	Rev. E
	Sheet 3 of 3

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APPENDIX

USE OF THE INFUSER IN ELECTROMAGNETIC ENVIRONMENTS

✓EN-2 The GemStar infuser (outside of the United States) is intended for use in the electromagnetic environment specified in *Electromagnetic Emissions*, *Electromagnetic Immunity*, and *Electromagnetic Immunity for Life-Supporting Equipment and Systems*. The user of the device should assure that it is used only in the appropriate environment.

ELECTROMAGNETIC EMISSIONS

Table A-1 details electromagnetic emissions compliance and guidance for the GemStar infusion device.

Table A-1. Guidance and Manufacturer's Declaration - Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Enforcement - Guidance
RF emissions CISPR 11	Group 1	The infuser uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The infuser is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

ELECTROMAGNETIC IMMUNITY

Table A-2 details guidance for the electromagnetic environment for the GemStar.

Table A-2. Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air (See Note 2)	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	± 2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% U_r (>95% dip in U_r) for 0.5 cycle 40% U_r (60% dip in U_r) for 5 cycles 70% U_r (30% dip in U_r) for 25 cycles 5% U_r (>95% dip in U_r) for 5 seconds	<5% U_r (>95% dip in U_r) for 0.5 cycle 40% U_r (60% dip in U_r) for 5 cycles 70% U_r (30% dip in U_r) for 25 cycles 5% U_r (>95% dip in U_r) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the infuser be powered from an uninterruptible AC mains power supply, or the batteries.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	400 A/m (See Note 3)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

Note 1: U_r is the AC mains voltage prior to application of the test level.

Note 2: Compliance levels tested to IEC 60601-2-24 requirements, which are more stringent than IEC 61000-4-2.

Note 3: Compliance levels tested to IEC 60601-2-24 requirements, which are more stringent than IEC 61000-4-8.

ELECTROMAGNETIC IMMUNITY FOR LIFE-SUPPORTING EQUIPMENT AND SYSTEMS

Table A-3 provides guidance for use of the GemStar near communications equipment.

Table A-3.
Guidance and Manufacturer's Declaration -
Electromagnetic Immunity for Life-Supporting Equipment and Systems

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Immunity Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the infuser, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a]	$[V_1]$ V	Recommended separation distance $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$
	10 Vrms 150 kHz to 80 MHz in ISM bands[a]	$[V_2]$ V	$d = \left[\frac{12}{V_2}\right]\sqrt{P}$

Table A-3.
Guidance and Manufacturer's Declaration -
Electromagnetic Immunity for Life-Supporting Equipment and Systems

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Immunity Guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHZ to 2.5 GHz	$[E_1]$ V/m	Recommended separation distance: $d = \left[\frac{12}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{23}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). [b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [c] should be less than the compliance level in each frequency range. [d] Interference may occur in the vicinity of equipment marked with the following symbol:

Note: At 80 MHz and 800 MHz, the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.660 MHz to 40.700 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular and/or cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the infuser is used exceeds the applicable RF compliance level above, the infuser should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the infuser.

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_1]$ V/m.

RECOMMENDED SEPARATION DISTANCES FOR COMMUNICATIONS EQUIPMENT

The GemStar is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The recommendations provided in *Table A-4* help the user of the device to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the infuser, according to the maximum output power of the communications equipment.

Table A-4.
Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the GemStar

Rated Maximum Output Power of Transmitter (Watts)	Separation Distance According to Frequency of Transmitter (Meters)			
	150 kHz to 80 MHZ outside ISM bands $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = \left[\frac{12}{V_2}\right]\sqrt{P}$	80 Mhz to 800 MHz $d = \left[\frac{12}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{23}{E_1}\right]\sqrt{P}$
0.01	0.035	0.12	0.12	0.23
0.1	0.11	0.38	0.38	0.73
1	0.35	1.2	1.2	2.3
10	1.1	3.8	3.8	7.3
100	3.5	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.				

Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note: The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.695 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.660 MHz to 40.700 MHz.

Note: An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structure, objects, and people.

Note: V_1 = 10 Vrms, V_2 = 10 Vrms, and E_1 = 10 V/meter.

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WARNING: EXPLOSION HAZARD EXISTS IF THE INFUSER IS USED IN THE PRESENCE OF FLAMMABLE SUBSTANCES.

CE 0050 — Indicates compliance of this device to the Medical Device Directive 93/42/EEC.

Class 1 — Mains supply equipment using protective earth.

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